High-value Specialty Medicines are DRIVING GROWTH IN THE GENERICS MARKET

Trending now: Emerging markets are the next big opportunity after the United States.


Sanjeev Kumar

INCREASED LIFE expectancy, a growing older-population cohort, and the higher incidence of chronic lifestyle-related diseases are encouraging the use of generic pharmaceuticals as governments and healthcare service providers strive to contain costs. Impending patent expiries of key drugs and a promising pipeline of next-gen high value-added biosimilars will sustain double-digit growth for generics.

On the flip side, increasing global competition, downward pricing pressure, and tightening regulations will challenge market participants. Further, professionals and patients often prefer branded drugs over generics. Using innovative production platforms to develop lower cost biosimilars as well as a premium priced portfolio can offer greater mileage to generics companies.

Recent analysis from Frost & Sullivan finds that generic drugs earned revenue of $330.87 billion in 2015, with a 37% share of the global pharmaceutical market. This is expected to reach $557.37 billion by the end of 2020. In fact, the generics segment is growing at a CAGR of 11% for this period, while the global pharmaceutical market is growing at a lower CAGR of 9.8%. By 2020, specialty and biosimilars will account for up to 70% share of generics.

"Patent expiration and increased usage of traditional generic drugs are curbing the cost of drugs, compelling the industry to invest in specialty medicines," says Frost & Sullivan transformational health industry manager Sanjeev Kumar. "With innovation and technology, generics can be enhanced to deliver additional benefits."

New Report Identifies Most Expensive Specialty Drugs

RGA Reinsurance Company, a subsidiary of Reinsurance Group of America, has released a report identifying 183 high-cost specialty drugs, defined as costing greater than $50,000 annually or $7,000 monthly, based on wholesale acquisition costs (WAC) of each product identified.

The most expensive drugs in annual cost include:

- Ravicti, indicated for the treatment of urea cycle disorders ($793,632)
- Lumizyme, indicated for the treatment of Pompe's Disease ($626,400)
- Carbaglu, indicated for hyperammonemia ($585,408)
- Actimmune, for the treatment of severe, malignant osteopetrosis and chronic granulomatous disease ($572,292).

Half of U.S. Postmarketing Studies are Commitment Trials


Natalie DeMasi

A new study published by Cutting Edge Information found that on average, just over half of all U.S. postmarketing studies are commitment studies as opposed to just 11% of other country-level teams' studies. This trend is likely due to the increasing number of products that receive expedited approval in the United States is contingent on future postmarketing studies. From a global standpoint, 32% of postmarketing studies are commitment trials.

There are notable differences in the percentage of postmarketing studies that demonstrate cost-effectiveness. On average, one-tenth of global teams' Phase IV studies have a primary goal of collecting health economics data, while 16% and 4% of country-level and U.S. teams do, respectively. Previous research conducted by Cutting Edge Information found that HEOR data is far more critical in the EU than in the United States, further supporting this data.

"Different regions may have different treatment practices, and patient populations vary based on subpopulation geographies," says Natalie DeMasi, research team leader at Cutting Edge Information. "Goals will also vary based on the product's lifecycle, competition, and payer needs. However, postmarketing studies at the regional level will help companies gather local data critical for understanding regional prescribing patterns, patient adherence, and potential marketing extensions."

Regulatory Affairs Plays Increasingly Strategic Role

Regulatory professionals are spending more of their time on strategic activities and less time on tasks related to research and development, clinical testing, product registration, and other preapproval activities, according to a survey by The Regulatory Affairs Professionals Society (RAPS). Overall, compensation has increased, but more for those at mid-level positions, than those at senior levels, and those same mid-level professionals benefit most from having earned the Regulatory Affairs Certification (RAC).

Regulatory professionals' compensation was found to be most affected by job level and several other related and interdependent factors, including regulatory experience, highest-earned degree, total professional experience and, for mid-level professionals, whether they have the RAC credential. RAC holders earn an average of 11% more in base salary than their peers without the RAC credential. For the first time since RAPS began conducting this research, regulatory experience was shown to have a greater impact on compensation than highest-earned academic degree.

Most regulatory professionals have multiregional or worldwide responsibilities, and work with multiple types of healthcare products. More than 88% of regulatory professionals began working in another field before transitioning into regulatory, and most have significant prior professional experience, usually in a related field.

More than 99% have a university degree, and more than 84% hold a degree in a clinical discipline, science, or engineering. More than 42%

Therapeutic trax

Autoimmune

The global market for therapies for rheumatoid arthritis is expected to grow from $19.9 billion in 2015 to nearly $21.3 billion by 2020, reflecting a five-year CAGR of 1.3%. As a therapeutic class, anti-interleukin biologics should grow from about $1.2 billion in 2015 to $1.5 billion in 2020 on a five-year CAGR of 4.4%. Biosimilars as a therapeutic class should reach $5.4 billion in 2020 on a five-year CAGR of 71.0%, up from an anticipated $368 million in 2015.

Source: BCC Research

The rheumatoid arthritis pipeline is relatively large, containing 454 products. While the proportion of first-in-class products in the pipeline is marginally lower than the industry average, it contains many first-in-class targets that have the potential to lead to therapeutic advances. In particular, there is a higher proportion and diversity of first-in-class molecular targets in the early development stages than in the clinical trial development stages.

Source: GBI Research

Cardiovascular

The atrial fibrillation market will expand from about $8 billion in 2015 to hit its peak of $11.8 billion in 2022, after which the impact of patent expiries will see the market value fall rapidly to $4.9 billion by 2025. The market, which covers the eight major markets of the U.S., France, Germany, Italy, Spain, U.K., Japan, and Canada, will decline after 2022 due to the entry of the first generics of the new oral anticoagulants (NOACs), starting with Boehringer Ingelheim's anticipated loss of U.S., Japanese, and Canadian patent protection for Pradaxa in 2018.

Source: GlobalData

The therapeutics market for venous thromboembolism (VTE), a condition that comprises deep vein thrombosis and pulmonary embolism, is set to rise from $2.8 billion in 2015 to $3.7 billion by 2025, representing a CAGR of 2.89%. This growth, which will occur across the seven major markets of the U.S., France, Germany, Italy, Spain, the U.K., and Japan, will be driven primarily by the rise in sales surrounding the VTE primary prophylaxis space, which is projected to increase from $2.4 billion in 2015 to $3.5 billion by 2025, at a CAGR of 4.01%.

Source: GlobalData

The global hypercholesterolemia drugs market is expected to decline at a CAGR of close to 7% during the period 2016-2020, due to the entry of generics in the market as the marketed drugs have lost their patents. In addition, product recalls and withdrawals by the FDA are a challenge and negatively affect drug manufacturers in the market. For instance, in January 2014, Merck initiated a voluntary nationwide user-level recall of Liptruzet. In June 2015, the FDA discontinued this product from the market due to its safety issues. However, the decline is partially offset by the rising risk of CVDs.

Source: Technavio

The global heparin market stood at $8.2 billion in 2014. Rising at a CAGR of 6.3% from 2015 to 2023, the market is expected to reach $14.3 billion by the end of 2023. The demand for low molecular weight heparin (LMWH) was the highest in the market in 2014. By 2023, the LMWH segment is expected to reach $12.3 billion. Regionally, North America emerged as the dominant segment in 2014. The rising incidence of DVT and pulmonary embolism (PE) will enable the North America market to exhibit a CAGR of 5.9% between 2014 and 2023.

Source: Transparency Market Research

Dermatology

The global dermatology market was valued at $20.0 billion in 2015, and is projected to grow at a CAGR of 7.73%, reaching $33.7 billion in 2022. Key drivers of this growth will be the uptake of recently approved premium biologics, as well as promising late-stage products that are expected to be highly valuable.

Source: GBI Research

The psoriasis market is set to rise from $6.4 billion in 2014 to $12.6 billion by 2024 at a CAGR of 7.05%. This growth will be driven by the launch of novel psoriasis products, uptake of biosimilars for currently marketed biologics, and the expansion of existing psoriasis therapies such as dimethyl fumarate from Germany into the U.S. and major European markets.

Source: GlobalData

continued

have a master's degree, and more than 20% have a doctorate.

Global Bioinformatics Market to Grow

The global bioinformatics market is expected to grow at a CAGR of 15.5% between 2014 and 2020, reports Transparency Market Research in a new study. The market was valued at $10.04 billion in 2013 and is projected to reach $30.87 billion by the end of 2020. The drug development segment is anticipated to lead all application segments. North America is expected to maintain its dominance in the global bioinformatics market with a revenue of $11.92 billion by 2020. Asia Pacific is expected to witness the highest growth with a CAGR of 18.7% throughout the forecast period.

The implementation of expansion strategies to enhance market share will increase the intensity of competitive rivalry on the global level for the existing market players. To maintain their position in the global bioinformatics market, the large number of market players operating in the global bioinformatics market are investing in research and development projects. They are also looking forward towards technological advances for increasing application in biosciences and integrated information technology. The top three market players in the global bioinformatics are Affymetrix, Accelrys, and CLC bio. They together comprise about 34.6% of the overall global bioinformatics market in 2014. PV

Therapeutic trax

Hormone Replacement

The global testosterone replacement therapy market is expected to decline at a CAGR of more than 3% during the period 2016-2020. The testosterone replacement therapy market in the the Americas is declining at a substantial CAGR of close to 15% to drop from $2 billion to $900 million by 2020. However, despite the decline, Americas will remain the major market for testosterone replacement therapy during the forecast period.

Source: Technavio

Infections

The global anti-infective agents market is expected to reach more than $111.4 billion by 2024. The rising prevalence of infectious diseases such as HIV, H1N1, and ebola virus reflect the profound changes in behavioral patterns of communities over the recent decades. The antibacterial segment was observed to account for the largest share of over 54% in 2015. The anti-viral agents segment is expected to grow at a swift CAGR of over 3.5% owing to the high price associated with the introduction of new potent anti-viral drugs such as Vicriviroc for HIV treatment purpose. North America dominated the overall anti-infective agents market in terms of revenue of more than $25.0 billion in 2015.

Source: Grand View Research

The global methicillin-resistant Staphylococcus aureus (MRSA) drugs market from 2016-2020 is expected to grow at a CAGR of 1.3%. The rise in the development of multidrug-resistant pathogens, coupled with the limited number of drugs available for treatment, has resulted in the Generating Antibiotics Incentives Now (GAIN) Act. As per this act, any drug being developed to treat qualified infectious diseases will be granted a qualified infectious disease product (QIDP) designation, which will help the company attain fast track designation and priority review by the FDA.

Source: Technavio

Ophthalmology

A range of new company entrants into the ophthalmological disorders market is forecasted to almost double the market from $13.7 billion in 2015 to $26 billion by 2020, at a CAGR of 9.48%. The ophthalmology landscape will see key companies lose dominance in favor of smaller and specialized companies gaining entrance.

Source: GBI Research

Pain

The active pain pipeline is populated by 810 products across all stages of development, which exhibit a highly diverse range of molecular targets. There are 129 first-in-class programs in active development, constituting 20% of the pipeline for which there is a disclosed molecular target, and acting on 80 first-in-class molecular targets.

Source: GBI Research

Respiratory

The market size for respiratory therapeutics, covering asthma, chronic obstructive pulmonary disease, idiopathic pulmonary fibrosis, and cystic fibrosis, is expected to rise considerably from $28.1 billion in 2015 to $46.6 billion by 2022, at a CAGR of 7.5%.

Source: GBI Research

The idiopathic pulmonary fibrosis (IPF) market is forecast to grow during the 2015-2025 forecast period, from sales of $907.3 million in 2015 to $3.2 billion in 2025. As promising Phase II drugs are developed and approved, the IPF market will evolve, due to the improvements offered by these newer drugs.

Source: GlobalData

Transplant

The global market for graft-versus-host disease treatment will increase from $295.7 million in 2013 to $544.6 million by 2023, a CAGR of 12.8%. This growth, which will occur across the six major markets of the US, France, Germany, Spain, Italy, and the UK, will be driven by the rising number of allogeneic hematopoietic stem cell transplantations and the increasing use of marketed and off-label biologic therapies.

Source: GlobalData

Oncology Corner...

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

Global Cancer Market to Grow, Fueled by Record Level of Innovation


Murray Aitken

More than 20 tumor types are being treated with one or more of the 70 new cancer treatments that have been launched in the past five years, with the sustained surge in innovative therapies driving the global oncology market to $107 billion in 2015. However, many of these drugs are not yet available to patients in most countries, and even when registered they may not be reimbursed under public insurance programs, according to a new study released by the IMS Institute for Healthcare Informatics.

The study finds that growth in global spending on oncology therapeutics and supportive care drugs increased 11.5% on a constant-dollar basis last year. A large and diverse set of more than 500 companies is actively pursuing oncology drug development around the world. Collectively, they are advancing nearly 600 new molecules through late-stage clinical development, most frequently for non-small cell lung cancer and breast, prostate, ovarian and colorectal cancers.

Annual global growth in the oncology drug market is expected to be 7.5% and 10.5% through 2020, reaching $150 billion. Wider utilization of new products — especially immunotherapies — will drive much of the growth, offset by reduced use of some existing treatments with inferior clinical outcomes. Payers also are expected to tighten their negotiation stance with manufacturers and adopt new payment models in an effort to drive greater value from their expenditures on these drugs.

"The new science redefining cancer as a large number of narrowly defined diseases and yielding therapeutic options for an expanding number of patients is rapidly transforming the oncology treatment landscape," says Murray Aitken, IMS Health senior VP and executive director of the IMS Institute for Healthcare Informatics. "Most health systems are struggling to adapt and embrace this evolution — including the regulatory systems, skilled professionals, diagnostic and treatment infrastructures, and financing mechanisms that are required to serve the needs of cancer patients around the world. These challenges demand urgent attention in light of the strong near-term pipeline of clinically distinctive therapies, and new programs such as the U.S. government's cancer moonshot that are galvanizing research efforts to change the trajectory of cancer."

Health Plan Restrictions Keep Cancer Patients from Getting Treatments

A national survey of patients with hard-to-treat cancers finds health plans routinely deny claims, drop drugs from the formulary after the plan-year has begun, and employ practices such as step-therapy or fail first to force patients to take less effective treatments despite the best advice from their physicians. At the same time, most patients (61%) report higher monthly premiums for their health coverage than a year ago, and a dramatic hike in their out-of-pocket payments, according to the recent survey conducted by Patients Rising, in partnership with CancerConnect.


Jonathan Wilcox

Half of all respondents (47%) and a greater majority (73%) of those 18 to 44 say that dealing with insurance problems is time-consuming and stressful and 61% agree that cancer patients who have trouble affording co-insurance payments will often take a different drug or no drug at all.

Jonathan Wilcox, Patients Rising policy director and co-founder says, "This survey shows that because of many insurance practices, too often patients don't receive the type of care they pay for and deserve. The insurance industry needs to listen to these constructive complaints and improve the overall quality of its service."

Highlights of the poll regarding the cost of cancer treatment include:

- Among cancer patients between 18 and 44 years old, 91% have seen premium hikes over the past year, with 45% of them reporting increases of more than $100 a month.
- At the same time, a majority of cancer patients (54%) say their medical insurance deductible has risen over the past five years. The average deductible increase is $898, with 18-44-year-olds seeing an increase of $1,549.
- Claim denials are a common occurrence; 57% of patients faced denied claims, and 27% of those aged 18-44 had five to six rejected claims.
- 86% of those surveyed want to have access to targeted therapies recently approved by the FDA called immunotherapies that free up the body's immune system to recognize and destroy specific cancer cells.
- 83% say "Not getting to take the drug your doctor prescribed can mean taking a less effective treatment or one with more side effects," and 35% of those surveyed say, "Many cancer patients are required by their insurance plan to take a different drug than the one their oncologist thought was best."
- 77% believe that step therapy or fail first causes cancer patients to take potentially ineffective treatments instead of the therapy prescribed by the oncologist.
- A majority of respondents, 52% say prior authorization is often reviewed by an insurance representative without medical training.
- 70% of cancer patients surveyed say that when they began cancer treatments that they did not know which therapies were included in their health plan's formulary.

Cancer Trax

The glioblastoma treatment market will increase five-fold from $659 million in 2014 to $3.3 billion by 2024.This meteoric 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. Japan will see the most impressive relative growth, with sales expanding from $47 million in 2014 to $268 million in 2024; this growth will be driven by the introduction of new drugs such as Opdivo.

Source: GlobalData

The market for renal cell carcinoma (RCC), a form of kidney cancer, is set to rise from $2.1 billion in 2013 to $3.6 billion by 2023, representing a CAGR of 5.6%. This growth, which will occur across the eight major markets of the U.S., France, Germany, Italy, Spain, the UK, Japan, and China, will be driven by a number of factors including the rapid uptake of immune checkpoint inhibitors and combination regimens, and a considerable 63% increase in the incidence of RCC in the 8MM over the forecast period.

Source: GlobalData