

MarketLine

Global Pharmaceuticals Market

Value Chain Analysis

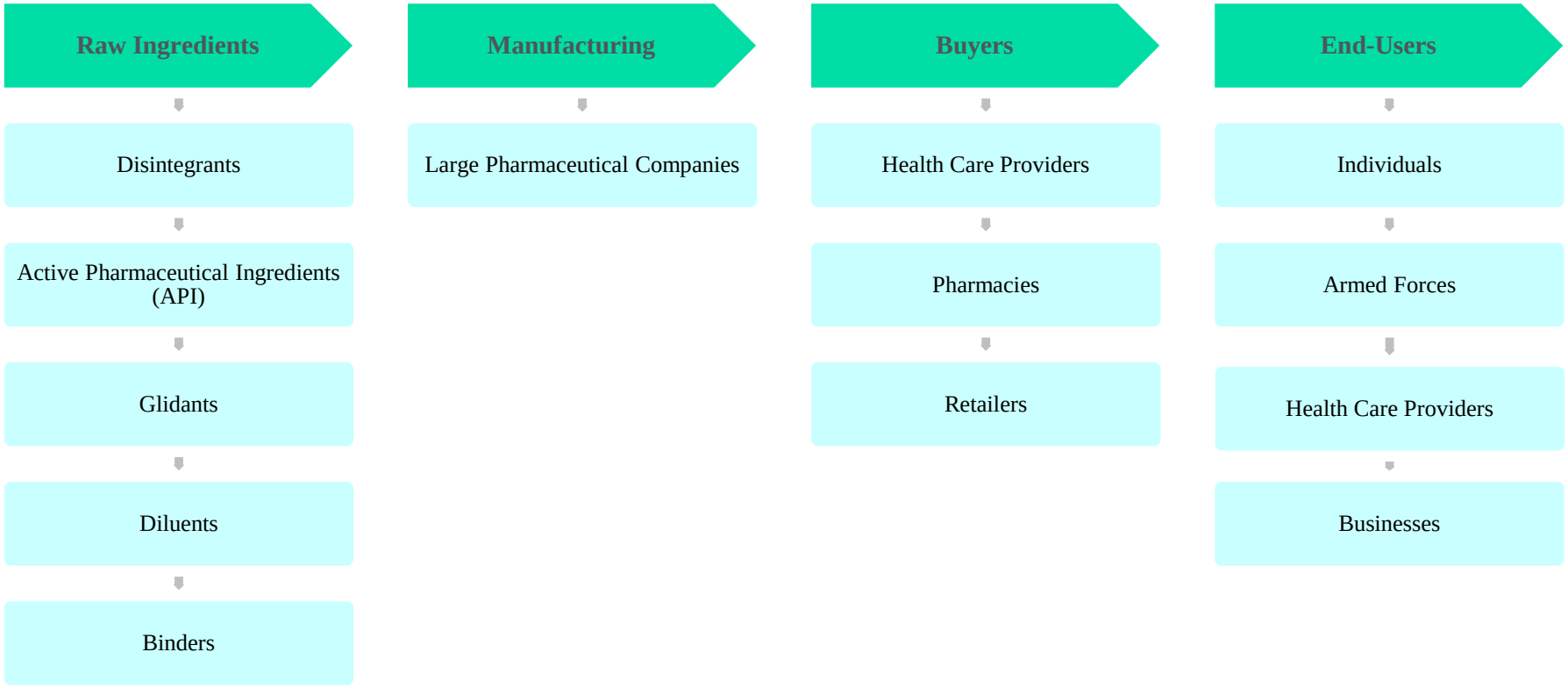
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Complete Value Chain: Overview

The value chain for pharmaceuticals can be divided into four segments: raw ingredients, manufacturing, buyers and end-users.



Complete Value Chain: Overview (cont'd)

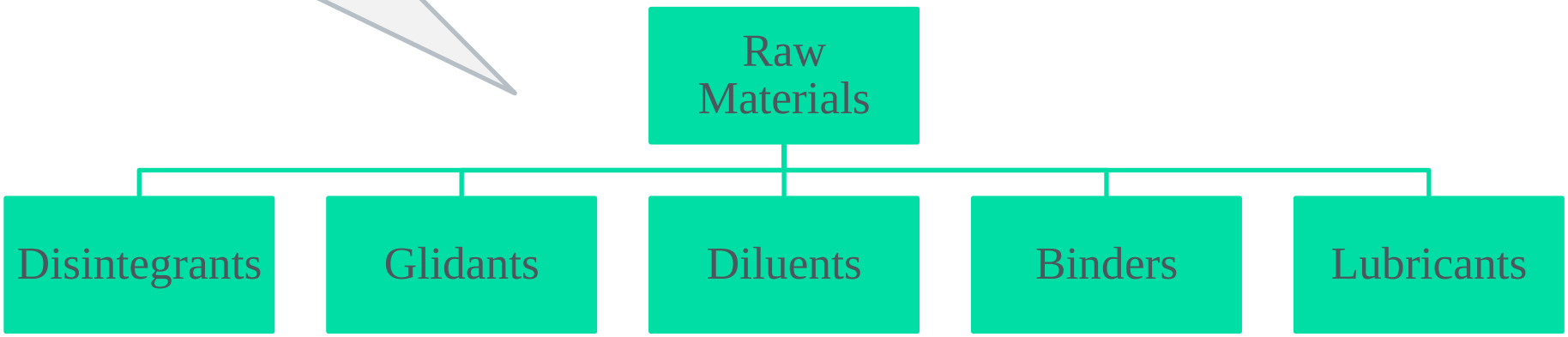
The value chain for pharmaceuticals can be divided into four segments: raw ingredients, manufacturing, buyers and end-users. Each of the first three segments are heavily influenced by the actions of very large international companies.

Raw Ingredients	Manufacturing	Buyers	End-Users
Teva Pharmaceutical	Teva Pharmaceutical	United Healthcare	Individuals
BASF	Novartis	National Health Service	US Army
Dr. Reddy's Laboratories	Bayer	CVS Corporation	National Health Service
Aurobindo	Johnson & Johnson	Walgreens	
Sandoz (Novartis subsidiary)	Pfizer	Abbott	

Raw Ingredients: Overview

Raw ingredients for pharmaceuticals are often made by the leading pharmaceutical companies. Given the vast number of ingredients used it is not realistically possible for any one company to produce them all.

Raw materials in drugs are legion but can be loosely collected into various groups, which in turn can be sub-divided further into many more than are possible to list here.



Raw Ingredients: Analysis

Raw ingredients in pharmaceuticals are very wide-ranging in scope but can be loosely combined into groups. Pharmaceutical companies are responsible for sourcing ingredients.

- Pharmaceutical companies have backwards integrated into the creation of ingredients for generics to reduce the costs of manufacturing and help to improve the security of supply. This is not only the case for excipients (non-active ingredients) but for active pharmaceutical ingredients (APIs) too.
- Teva for example has its own standalone business unit called TAPI (Teva Active Pharmaceutical Ingredients) which produces more than 370 APIs and Dr. Reddy's has over 60 APIs. Pharmaceutical companies enter into contractual agreements with suppliers, and they may therefore incur switching costs if they decide to change supplier.
- Pharmaceutical companies will likely be more keen to backwards integrate in APIs because those ingredients are essential to producing the final generic drug and are therefore going to be most in demand. However, that does not mean backwards integration in excipients is not valuable to leading companies – the quantities required for mass manufacturing make them important.
- The willingness to backwards integrate is important due to the potential cost reductions that can be found by doing so. Many healthcare systems around the world are advocating for ever greater use of generics on cost grounds, meaning there are clear incentives for companies to backwards integrate as far as possible into raw ingredients.
- APIs may also be sold by chemical companies, such as BASF.

Raw Ingredients: Burning Issue

European Commission has tightened rules regarding penalties for companies falsifying medicines, active substances and excipients.

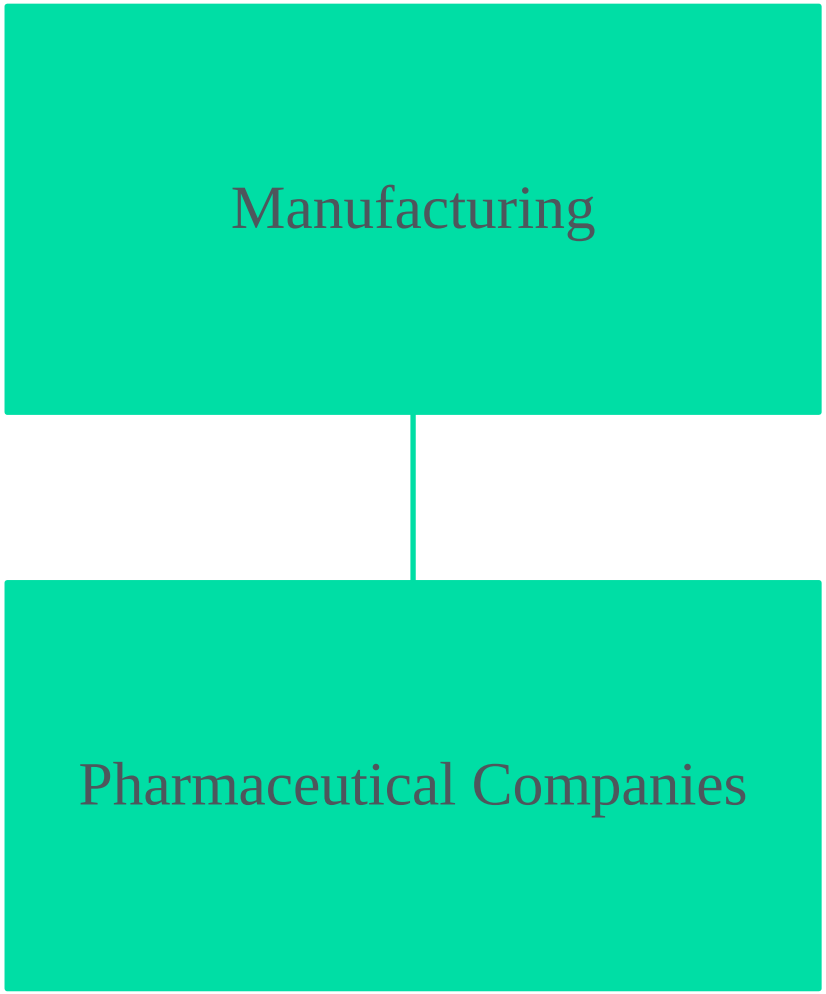
The European Commission published a report in February 2018 in which it was found EU member states 'have satisfactorily strengthened their laws to assess penalties for companies falsifying medicines, active substances and excipients.' 26 of the 28 member states changed legislation and created prison sentences and fines for transgressors. However, the range of sentences and fines that can be issued in each country varies considerably: in Sweden the falsification information sentence is only one year; in Austria the maximum is stretched to 15 years. Fines vary similarly. For raw ingredients this is important because it places extra strain upon the security of the supply chain. The European Commission describes a falsified medicine as 'fake medicines that pass themselves off as real, authorized medicines.' For leading pharmaceutical companies the need to ensure all ingredients are sourced responsibly to avoid the punishments now possible has been heightened.



Moreover, the new European databased Medicines Verification System (MVS) implemented in 2019 aims to prevent falsified medicines from entering the legal supply chain. According to estimates, about 2500 pharmaceutical companies should be connected to the European wide database, EU Hub, when the implementation takes place.

Manufacturing: Overview

Manufacturing is dominated by major international pharmaceutical companies.



Manufacturing: Analysis

Manufacturing of pharmaceutical drugs is typically undertaken by large, international pharmaceutical companies.

- Pharmaceutical companies dominate the manufacture stage due to the economies of scale that many are able to achieve. Companies such as Teva Pharmaceutical Industries have backwards integrated throughout the supply chain, reducing costs and gaining complete control over the manufacturing process.
- A company wishing to market its products must demonstrate that its drugs are safe and effective, to the satisfaction of the national regulator. Examples of regulators include the Health Sciences Authority in Singapore, India's Drug Standard Control Organization, and the Pharmaceutical and Medical Devices Agency in Japan.
- Meeting these regulatory requirements is time-consuming; it can take 10-15 years to bring a drug to market. According to the Pharmaceutical Research and Manufacturers of America (PhRMA) for example, out of 5,000 to 10,000 screened compounds, only 250 enter preclinical testing, of which only five enter human clinical trials, and finally just one will be approved. In addition to investing a significant amount in research and development, manufacturers also expend substantial funds on marketing, which further increases the capital required.
- The main substitutes to branded drugs are generics and biosimilars (also known as follow-on biologics). Manufacturers of generics can offer the same drug at a much lower price, as they rely on the safety and efficacy data provided by the innovator product, and they therefore do not have to conduct costly clinical trials.

Manufacturing: Burning Issue

COVID-19 affects the pharmaceutical supply chain

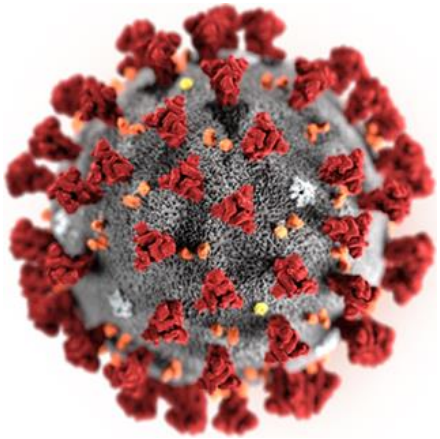
The COVID-19 pandemic is affecting a number of industries across the globe and is also impacting the global pharmaceutical supply chain. There is growing concerns about medicine availability during the global outbreak.

China and India, are two of the largest global producers of active pharmaceutical ingredients (APIs) and generics and restrictions in these countries is affecting the supply chain. Since the outbreak started in China and lockdowns were imposed, supply from their manufacturing facilities has reduced. Large manufacturing facilities have started to resume, however smaller producers may continue to struggle for some time.

While many publicly traded companies have six months to a year of stockpiles; if restrictions continue for an extended period of time, eventually supply chain shortages will start to disrupt everyone.

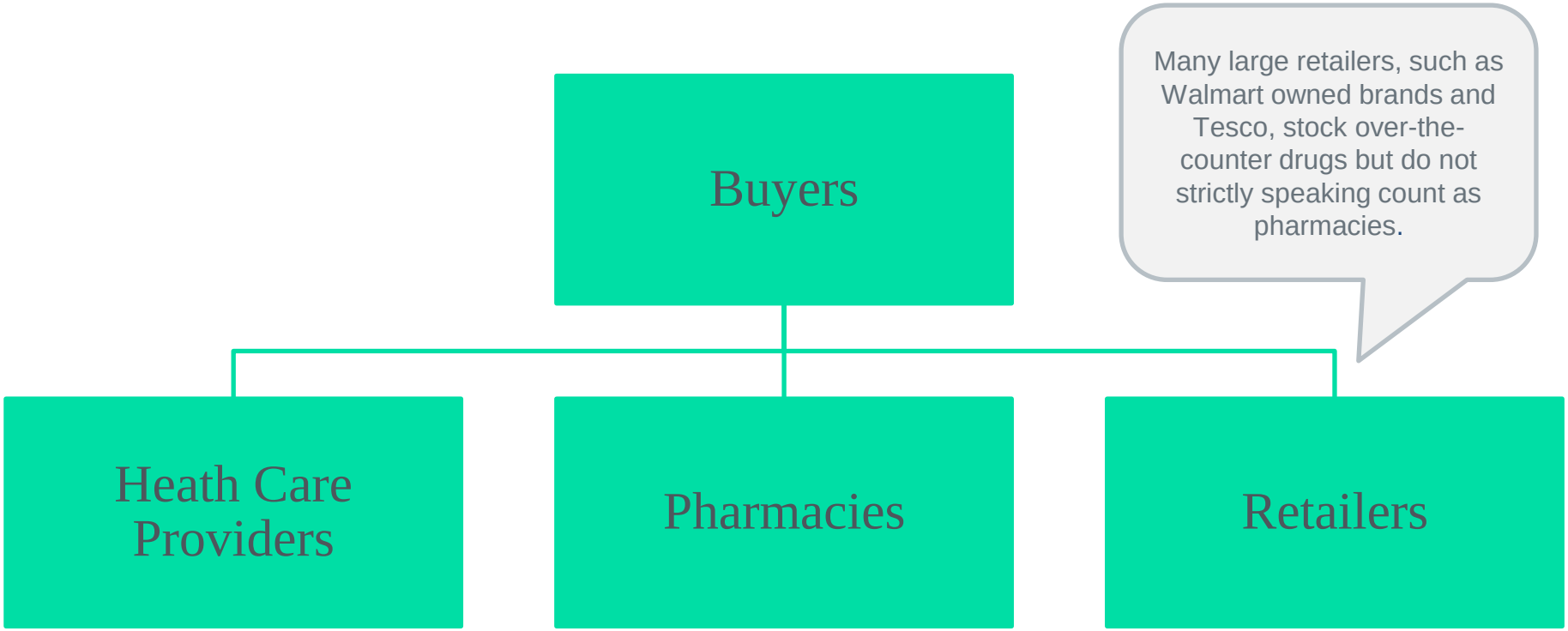
Moreover, in March 2020, the Indian government announced it had restricted the export of 26 active pharmaceutical ingredients which represents about 10% of their export capacity, according to FDA. The primary reason behind the export restrictions was to prevent domestic shortages in India in the long-term.

According to the European Pharmaceutical Review. following the aftermath of this pandemic, companies may begin to spread production across different markets, limiting the effects of future disruptions.



Buyers: Overview

Buyers in the market primarily consist of heath care providers, pharmacies and retailers. Each segment is dominated by large leading companies.



Buyers: Analysis

Health care providers make the majority of pharmaceutical purchases, but pharmacies and retailers remain important buyers for pharmaceutical companies.

- Health care providers are the major purchasers of pharmaceutical drugs due to that being the primary route by which most end-users need the products. Globally most people receive heath care through a mixture of private insurance and state funded support, enabling major health care companies to buy commonly required drugs in large quantities.
- However, pharmaceuticals are generally considered necessities despite increasing costs. While some public health agencies have strived to use generics where possible to lower costs, for newer treatments patents lead to higher costs.
- Pharmacy chains are common places for end-users to buy generic drugs, making companies such as Boots large buyers of pharmaceutical drugs. Ethical drugs require a prescription from a doctor or dentist.
- Marketing of prescription drugs by their manufacturers is therefore largely directed at medical practitioners, with whom they wield a significant influence. In fact, with the notable exception of the United States, advertising such products directly to consumers is usually illegal.
- Other big buyers of generic drugs are retail stores such as Walmart and Tesco. Big retail chain stores such as these operate stores of sufficient size to have it commercially viable to sell generic drugs to the public. Some stores even have pharmacies located inside.
- Some independent pharmacies exist but these often operate on a small scale and supply isolated communities.

Buyers: Burning Issue

Governments are stepping up orders for generic drugs to take advantage of lower prices at a time when health care budgets are under severe pressure.

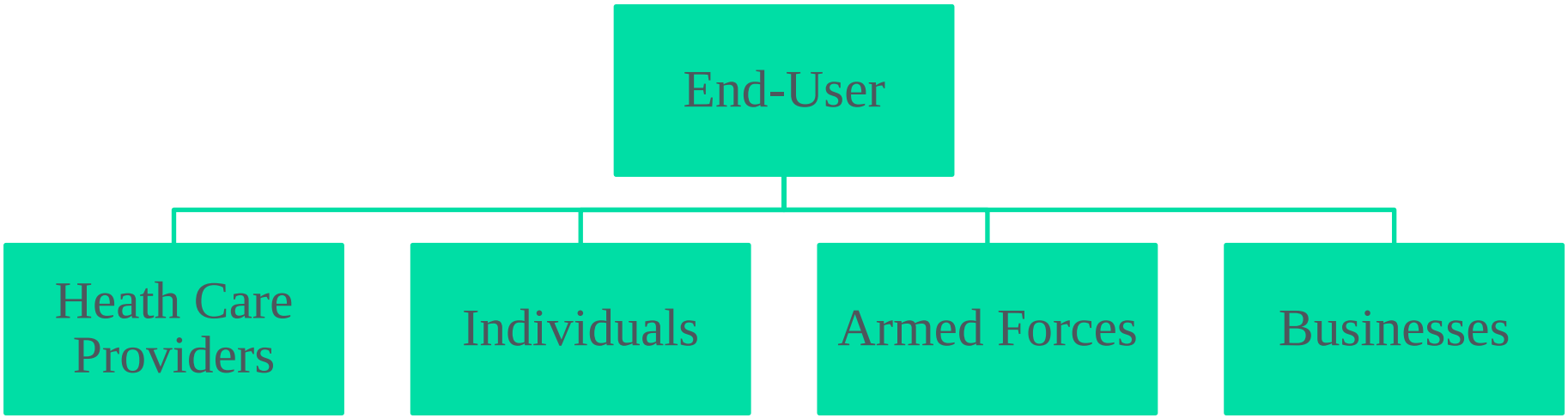
A major problem that health care systems around the world face is the cost of drugs, especially those intended for end-of-life care. Ageing populations and austerity drives in many countries have also forced healthcare providers to attempt to drive down costs. Since the passing of the Generic Drug Act in 2009 there has been a push in Brazil to increase usage, resulting in a steady decline in originator drugs. Helped by pro-generic drug campaigns funded by the Brazilian government, surveys have revealed approximately 83% of patients believe all generic/non-originator drugs have a similar efficacy and safety to branded drugs. Policymakers also face an uphill battle against lobbyists, particularly in the United States. The Center for Responsive Politics, an independent group that tracks money in politics, found that drugmakers spent $171.5m lobbying the federal government in 2017— more than insurance, electronics, oil and gas or any other industry.



Nonetheless, the pressure for cost reductions on generic drugs is rising. Even generic drugs in the US are notoriously expensive. Drug costs have nearly doubled in the last five years, growing from $1.1 billion in 2012 to nearly $1.9 billion. With the lack of a national healthcare system, the government can't always secure low prices; instead private insurers can negotiate with pharmaceutical companies directly meaning prices are usually high. As of 2017, a number of state attorney generals will have the ability to sue drug companies if they increase their prices unfairly which may mean more competition between generics and the original drugs. Two years after California passed its first-in-the-nation drug pricing transparency law, state officials have released data which showed pharmaceutical companies raised the wholesale acquisition cost of their drugs by a median of 25.8% from 2017 through the first quarter of 2019.

End-Users: Overview

End-users are dominated by individuals, but employers such as health care providers and armed forces frequently require generic drugs to protect the health of employees.



End-Users: Analysis

End-users are dominated by individuals, but employers such as health care providers and armed forces frequently require ethical drugs to protect the health of employees.

- Individuals are the leading end-user due to the vast scale of the need. Most will access pharmaceutical products directly through the health care system they pay into rather than purchase them from a pharmacy. According to the Center for Disease Control and Prevention (CDC), between 2013 and 2016 (most recently available data) 48.4% of people in the US took at least one prescription drug every 30 days. Three or more drugs was estimated at 24%.
- For end users, the majority of ethical drugs are restricted to access via a prescription from a doctor or dentist. The CDC estimates that in 2016, 73.9% of physician visits involved drug therapy, the primary therapeutic classes being analgesics, antihyperlipidemic agents, and antidepressants.
- The US is again unique in that it permits pharmaceutical manufacturers to market directly to consumers, a practice which is usually illegal in most countries.
- People who pay into private health care insurance are increasingly seeking out generic drugs as a cheaper alternative to patented drugs. This is especially true in the United States, where insurance premiums are notoriously high and drug prices are inflated beyond what is commonly paid overseas.
- Employers also constitute end-users. Many of those that require drugs to protect staff or to treat staff will be various armed forces or heath care operators working in hazardous environments. Instances in which employees are required to take pharmaceutical products are likely to be few in number, making employers small in respect to other end-users.

End-Users: Burning Issue

End-users in the US are increasingly struggling to afford access to healthcare.



According to MarketLine data, the US is the largest market for pharmaceuticals, accounting for over 38% of the global value in 2019. Increasingly byzantine insurance provision and increasing premiums and excesses has seen many US citizens struggle to access drugs. Estimates by the the Journal of the American Medical Association found per capita spending for prescription drugs in other nations ranged from $466 to $939. In the US, per capita spending was $1,443.

EpiPen, an allergy medicine produced by Mylan Pharmaceuticals, has increased in cost by about 600% since 2007. One of the more notorious cases was Turing Pharmaceuticals, headed by Martin Skkreli. In September 2015, Shkreli received widespread criticism when Turing obtained the manufacturing license for the antiparasitic drug Daraprim and raised its price by a factor of 56 (from US$13.5 to US$750 per pill). NextSource acquired the rights to Lomstuine in 2013, and has subsequently increased the price nine times in less than five years, from $50 a capsule to $768. There are an estimated 28 million US citizens without health insurance, and even more in the “underinsured” category. This refers to families paying substantial amounts to cost-share with insurers and cover everything the plan will not. This has led to some Americans being forced to crowdfund for access to healthcare. While this has also spread to other nations such as Canada, the UK, and Australia, it is generally for experimental treatments not prescribed by public providers. In the US, many crowdfund for access to basic medicine.

Appendix

Ask the analyst

We hope that the data and analysis in this presentation will help you make informed and imaginative business decisions. If you have any questions or further requirements, MarketLine's research team may be able to help you. The MarketLine Research team can be contacted at reachus@marketline.com.

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