

A Growth Shift for the Pharmaceutical Industry

(Source: an article prepared by Cheryl Swanson and published by the stock advisor, "the Motley Fool")

According to the IMS Health's Institute for Healthcare Informatics, worldwide spending for prescription branded drugs and generic medicines will jump 30% from 2013-2018 -- a compound annual growth rate of over 5% -- leading to US\$1.3 trillion in annual global drug sales. The market is also radically shifting position, with traditional strongholds, such as Japan and Europe, bowing to emerging markets, such as China. The result, the author suggests, is that healthcare investors need a new strategy; they need a way to keep an eye on emerging markets so they aren't left in the lurch because they don't understand the true engines for growth in their holdings.

The author provides a country-by-country look at what's happening with global pharmaceuticals, focusing on the five largest markets for pharmaceuticals, based on sales, in 2013:

No.5 - France: Total pharmaceutical sales in 2013: US\$37.2 billion. France has historically been a strong market for brand name drugs. In general, the culture highly values treatment with expensive medications, as seen by the fact that more than 90% of doctor visits in France end with prescriptions, a much higher rate than other countries. France's market growth has plateaued however, due to restrictions on retail pharmacy margins and regulation of drug prices. *IMS World Review Analyst* reports that the French market for pharmaceuticals only grew 1% from 2012 to 2013, down from 4% the previous year. For the record, even at 1%, France is one of the few remaining European markets that is not declining. If you look at the breakdown the European Union as a whole, "growth" is -1%. The shrinking of the EU market is a serious problem for Big Pharma. Not only is the EU an easy market to reach and understand, but Big Pharma's most innovative drugs, particularly pricey biologics, those are skewed toward populations who can afford them, such as you find in many EU countries. For instance, expenditures on targeted oncology drugs increased exponentially in Europe over the past decade, making the EU now responsible for 40% of the overall market for these drugs. By contrast, emerging countries like China prioritize much less expensive drugs for public health diseases.

No.4 - Germany: Total pharmaceutical sales in 2013: US\$45.8 billion. Germany is the leading pharmaceutical market in Europe, but its growth has also slowed significantly. The German drug sector is expected to expand at a modest 1.7% rate from 2015 to 2020, according to research and consulting firm GlobalData. While Germany was once considered a "free price" market, that came to an end in 2011. A reform measure known as AMNOG took effect that year. AMNOG requires that pharma companies prove added benefits of their new products, or face very low reimbursement rates. AMNOG also excludes some new drugs entirely. For instance, Gilead Sciences' blockbuster *idelalisib*, known also as *Zydelig*, is approved in the US, but Germany's tougher regulators insisted

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In Brief . . .

- ◆ Pharmaceutical wholesaler and retailer **PHOENIX group** (Germany) reported a 3.6% increase in revenue (to €22.6 billion / US\$ 24.7 billion) and EBITDA of €546.6 million / US\$ 598.5 million (+24%) for its fiscal year ended January 31st. Targeted acquisitions in the year, which contributed the results, included the purchase of the Dutch company *Mediq Apotheken Nederland B.V.* (with pharmacy, pharmaceutical wholesale, and pre-wholesale activities) and the purchase of the Slovakian pharmacy chain *SUNPHARMA*.

- ◆ Japanese wholesaler **Suzuken** reported net sales of ¥1,970 billion / US\$ 15.9 billion (-0.9%) and net income of 18 billion / US\$145 million (-11.8%) for its fiscal year ended March 31st.

- ◆ **McKesson Corp's** (US) **Health Mart** pharmacy business maintained its strong record of growth during fiscal 2015, ending the year with nearly 3,800 stores which represented approximately 15% growth over the prior year.

- ◆ The Australian government has introduced a new 5-year package designed to ensure patient access to medicines subsidized under the *Pharmaceutical Benefits Scheme* (PBS) while promoting the scheme's sustainability and the quality use of medicines. The PBS Access and Sustainability Package includes a one-time 5% cut in the price of single brand drugs, reductions in generic medicine prices, biosimilar substitution by pharmacists, and the delisting of certain nonprescription drugs and is expected to save A\$6.6 billion / US\$5 billion over the 5 year period.

- ◆ **Cardinal Health** (US) donated over US\$250,000 in supplies (including surgical packs, casting material, crutches and basic toiletries) and US\$25,000 to support **AmeriCares** relief and emergency preparedness efforts in Nepal. In addition, Cardinal Health's executives personally contributed to the relief effort by volunteering to join a team of doctors, nurses, paramedics and logistics experts headed to Nepal. Since 2008, Cardinal Health has donated more than \$100 million in medical products, which are often the most needed items in times of disaster, to its disaster relief partners.

- ◆ **Surescripts'** e-prescription network processed 6.5 billion US health-data transactions in 2014; more transactions in one year than both American Express (6 billion) and PayPal (4.2 billion).

(Sources: Drug Store News, PHOENIX, Scrip and Suzuken)

"added benefit of *idelalisib* is not proven." In addition, some pharmaceutical companies are opting voluntarily not to provide their new products to Germany, in the face of needing to prove not just that a drug is effective but that it improves standard of care.

No.3 - China: Total pharmaceutical sales in 2013: US\$86.8 billion. China accounts for 20% of the world's population. Assuming the country's goal of universal coverage for its 1.35 billion citizens by 2020 stays on track, China should make up 34% of the global growth in medication spending over the next five

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Growth Shift (cont.) . . .

years. In fact, many believe China is destined to become the world's biggest pharmaceutical market. Yet accessing the market in China has proven far more complicated than expected for drugmakers, with U.S.-approved drugs and expecting acceptance in the Chinese market entry having not materialized to the extent originally thought. China's regulatory environment is complex, its regions are highly diverse, and the country's poor intellectual property protection has created significant challenges.

Adding to the pressure is the current recession. In fact, while sales in China for the eight largest drugmakers in the market, including Pfizer, Merck & Co., and GlaxoSmithKline, climbed 40% in 2011, that growth dwindled to 20% in 2013, according to data compiled by Bloomberg. China is still the largest growth opportunity, however, and with billions of dollars behind their efforts, Big Pharma is making unusual alliances. Pfizer produces and markets more than 40 innovative drugs in China, with manufacturing facilities in Dalian, Suzhou, and Wuxi. It also has a stake in one of China's top drug distributors, Shanghai Pharmaceuticals, as well as a joint venture to develop generic drugs with Zhejiang Hisun Pharmaceuticals.

One of the biggest opportunities in China is the diabetes market. According to IMS Health, China's diabetes market is expected to grow 20% to reach US\$3.2 billion by 2016. Johnson & Johnson is hoping its first diabetes drug, *Invokana*, will find success in China. As the diabetes market gets ever more crowded in the U.S., Merck's blockbuster *Januvia* is losing sales, but it may experience a reversal in China, where Merck employs over 2,000 people. Other top U.S.-based drug companies with stakes in China include AbbVie Inc., Abbott Laboratories, Amgen, and Eli Lilly & Co. Many have joint ventures in China, as well as manufacturing facilities.

No.2 - Japan: Total pharmaceutical sales in 2013: US\$94 billion. Driven by the needs of a rapidly aging population, the world's third-largest economy is the world's second-largest drug market. Highly efficient drug reviews facilitate the rapid entry of new products into Japan, as seen by the country's rapid approval of *Opdivo* from Bristol-Myers Squibb, prior to its approval in the U.S.

Unfortunately, Japan's drug market has been declining rapidly as the economy struggles with stagnation, made worse by the triple disaster (earthquake, tsunami, nuclear leak) of 2011. The good news for Japan is that innovation in large-scale drug development is increasing. Traditionally, Japanese drug companies keep research in-house, but that has been changing recently. Takeda Pharmaceutical, Japan's largest pharmaceutical company, is set to increase its global footprint with the announcement of incoming CEO *Christopher Weber*, a former GlaxoSmithKline executive. Weber will become Takeda's CEO in June, which will make him the company's first foreign CEO. Appointing a foreigner to Takeda's top job is an indication in itself that Takeda is looking to international markets.

No.1 - U.S.: Total pharmaceutical sales in 2013: US\$339.7 billion. The annual amount spent per-person on prescription drugs in the U.S. averages \$1,000 -- more than twice as much as in countries like Canada, Germany, and Australia.

While the Affordable Care Act contains measures to control healthcare costs, it turns out that Americans not only spend more

per drug, they also take more drugs. Disease rates are higher because of lifestyle risks such as obesity, physical inactivity, and excessive alcohol use, according to the Centers for Disease Control and Prevention. Accordingly, rates of heart disease,

COPD, and diabetes are higher in the U.S. than in most developed countries.

Branded drugs take by far the biggest share of the healthcare drug budget, but a recent Wall Street Journal article pointed out that the price of a variety of generics has also been significantly rising. It's estimated that half of all small-molecule generics sold through retailers have become more expensive in the past 12 months. In some cases, price hikes exceeded 1,000%, and some even topped 17,000%.

The International Pharmaceutical Distribution Conference Scheduled For November

This year's International Pharmaceutical Distribution Conference (IPDC) will be hosted by GIRP (the European Association of Pharmaceutical Full-line Wholesalers), managed by HDMA (the U.S. association of pharmaceutical distributors) and sponsored and endorsed by IFPW. The conference will be held in Brussels, Belgium (the home of GIRP), on November 12-13 at the Steigenberger Wiltcher's hotel.

The business program will include topics such as: pharmaceutical traceability and verification systems; the impact of international trade agreements; and building collaborative supply chain partnerships. The conference also will provide discussions with a variety of European and American distribution and manufacturer executives on the challenges they face in an ever-changing industry.

René Jenny, president of GIRP, said, "The swiftly growing globalization of our industry is leading to an increased demand for international and intercontinental contacts. A joint conference between HDMA, IFPW and GIRP provides an excellent opportunity for the members of these three organizations to broaden their horizons and perspectives. I am sure that the members of our European Association GIRP will be interested to participate and benefit from it."

"As many pharmaceutical distributors and manufacturers look outside the U.S. to expand their portfolios and gain ideas to strategically build their businesses internationally, HDMA is continuing its efforts to bring together supply chain leaders from around the world to understand the opportunities and challenges of an increasingly globalized industry," said HDMA president and CEO John Gray.

"The 2015 IPDC promises to be a thought-provoking opportunity for executives to share the best operating practices and technical approaches used by today's wholesalers and manufacturers in the ever-globalizing pharmaceutical industry," said Mark Parrish, president, IFPW. "IFPW is delighted to partner with its members, HDMA and GIRP, to present valuable perspectives to the European pharmaceutical supply chain community, and promote an information exchange that will help lead to a safer and more efficient pharmaceutical supply chain on both sides of the Atlantic."