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Global Industry Trends

(Source: The U.S. 2016 International Trade Administration Top Markets Report)

Fast growing segments of the pharmaceutical market include biologics and generics. Biologics now account for over a third of all new drugs in clinical trials or awaiting FDA approval. U.S. generic drug sales reached an estimated US$70 billion, representing a quarter of the global market, due to a large number of drugs going off-patent and healthcare reforms favoring generics. Although generics make up only 22 percent of total prescription sales, its share of filled prescriptions has risen from 19 percent in 1984 to 88 percent in 2015. The high volume and low spending reflects an extremely competitive sector with low-cost imports adding increasing pressure on domestic generics producers. It also points to high saturation in the U.S. generics market, underlining the need to expand abroad for future growth opportunities.

Meanwhile, the innovative pharmaceutical industry is currently facing unprecedented challenges caused by slower sales growth, expiring patents, increasing competition from generics, shorter product life cycles, tighter regulations, adverse media coverage and reputational damage, and a decline in the number of new innovative drugs under development. Many are concerned that, despite enormous expenditure on R&D, the industry is producing far fewer new drugs and effective therapies than it did decades ago while sales and administration costs are rising. This concern has been mitigated to some extent with successful drug approvals reaching record highs over the last couple years. The industry is adjusting to a more competitive environment by shifting manufacturing and other operations overseas, revamping research pipelines, reducing employment, particularly in sales (but also in manufacturing and research), and organizing mergers and acquisitions (M&As). A long string of M&As over the last few years has led to a more concentrated global industry with both innovative and generics companies engaging in acquisitions of all sizes. Large firms often purchase smaller, more focused innovator companies for new drugs to accelerate the R&D process. The lines between innovator and generic companies or between pharmaceutical and biotechnology companies have become increasingly blurred, and most major multinationals now incorporate both biologics and generics subsidiaries in their portfolios.

As the prevalence of biosimilars grows, the high manufacturing and regulatory costs involved in developing these drugs further clouds traditional distinctions between innovative and generic business models and investment cycles. Most finished pharmaceuticals consumed in the United States are manufactured locally, particularly complex products such as biologics, or imported from Western European countries, such as Ireland, Germany and Switzerland. The United States is a major hub for drug manufacturing, as imports account for only around a quarter of the market by value. Nevertheless, the sheer size of the U.S. market

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- **Cardinal Health** reported fiscal results for Q2 2017. The company reported that revenue increased 5% to US$33.1 billion while GAAP operating earnings decreased 4% to US$542 million while non-GAAP operating earnings decreased 4% to US$701 billion. Separately, Chairman and CEO *George Barrett* was elected Chairman of the Health Leadership Council and will serve a two-year term. The Health Leadership Council represents an alliance of companies from across all sectors of American Healthcare. He succeeds Susan DeVore, President and CEO of Premier.
- Japanese wholesaler and distributor **Suzuken Co., Ltd.** announced the consolidated results of the first three quarters for the fiscal year ending March 31, 2017. Total net sales were US$14.2 billion, down 2.5% year over year and ordinary income was US$182.5 million, down 33.2% year over year.
- **Toho Holdings Co., Ltd.** announced its consolidated financial results for the first three quarters of 2017. Total net sales were US$ 8.28 billion, a decrease of 3.2% year over year. Measures to reign in medical expenses culminated in a 7.8% reduction in the NHI drug prices including exceptions to repricing measures for market expansion in April 2016. The company also promoted a shift to value-added services by continuing to provide customer support systems and services in an effort to contribute to the establishment of a comprehensive health system.
- Global information and technology services company **QuintilesIMS** reported financial results for 4th quarter and for year-end 2016 ended December 31st. Revenue was US$1.95 billion for the 4th quarter and US$5.36 billion for the full year, while full year combined company revenue was US$7.78 billion, an increase of 7.8% on a constant currency basis and 7.4% at actual foreign exchange rates. “For our 1st quarter as a combined company, we delivered a strong

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IFPW Takes on Role of Secretariat for Fight the Fakes Campaign

As Fight the Fakes (www.fightthefakes.org) enters its fourth year, the Campaign was pleased to announce the rotation of its secretariat to the International Federation of Pharmaceutical Wholesalers (IFPW), and made possible through the support of IFPW Foundation. Since its launch in 2013, the campaign’s secretariat has been held by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), who have built the coalition to include international bodies representing healthcare professionals, academia, NGOs, the generic and research-based pharmaceutical industry, healthcare distributers, and consumer protection organizations.

Fake medicines are a danger to public health. By circumventing medicines regulatory authorities and passing

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means that imports were valued at over US$86 billion in 2015, making it the world's largest importer of pharmaceuticals. U.S.'s top five sources of pharmaceutical imports in 2015 were: 1. Ireland - US$15.2 billion; 2. Germany - US$14.5 billion; 3. Switzerland - US$9.4 billion; 4. Israel - US$6 billion; 5. India - US$6 billion.

With US$47 billion in exports in 2015, pharmaceuticals rank as one the top exporting sectors for IP-intensive industries in the United States. The largest export markets include Belgium, the Netherlands, Canada, the UK and Japan. Projecting forward, the increasing use of low cost manufacturing bases for foreign-derived sales will inhibit the export potential of U.S. manufacturers, and patent expiries for high value export products will place negative pressure on value. Despite these pressures, high levels of R&D may provide new products for export growth in the long-term as will increasing penetration into emerging markets. U.S.'s top five export destinations for pharmaceuticals in 2015 were: 1. Belgium - US$6.4 billion; 2. Netherlands - US$4.2 billion; 3. Canada - US$3.8 billion, 4. U.K. - US$3.7 billion; 5. Japan - US$3.5 billion.

It should be noted that U.S. trade statistics do not fully reflect the globalized nature of the pharmaceutical industry, which procures ingredients and manufactures in locations based on cost and quality, among other factors. For example, most of the low cost active pharmaceutical ingredients and excipients used in finished drugs in the United States are manufactured abroad, particularly in China and India. Products and substances may cross borders at several points in the manufacturing chains. Due to product perishability and supply chain costs, foreign companies tend to have substantial manufacturing operations in the United States to better access the market. Likewise, there is significant US industry production of pharmaceuticals in foreign markets, such as Ireland and Singapore, from which companies export to third countries. There are also a growing number of product-based strategic alliances and joint ventures between U.S.- and non-U. S.-headquartered drug companies.

The worldwide market for pharmaceuticals is projected to grow from around US$1 trillion in 2015 to US$1.3 trillion by 2020, representing an annual growth rate of 4.9 percent. Several global demographic and economic trends are driving pharmaceutical consumption, including a rapidly aging world population and an associated rise in chronic diseases, increased urbanization and higher disposable incomes, greater government expenditure on healthcare and growing demand for more effective treatments.

The primary pharmaceutical export markets in the near-term will continue to be in the traditional strongholds of North America, Western Europe and Japan, which have high per capita spending rates on healthcare, strong IP protections and streamlined regulatory processes. Growth rates in these developed economies, however, are projected to hover in the low to mid-single digits due to stagnating national economies, tighter regulations, patent expiries and pricing pressure.

In an era of global fiscal austerity, the industry expects foreign governments, particularly in Europe, to continue to put pressure on drug prices through 2017 and beyond, as the high visibility of drug prices makes them a relatively easy target for healthcare providers trying to reduce costs. Even in the United States, the rapidly rising cost of healthcare is resulting in political pressures and regulatory efforts to contain costs that could significantly affect the industry's bottom line. Comparative effectiveness determinations and value-based pricing are also starting to be mandated by some countries and insurers, who require evidence of cost savings or a clear clinical benefit before including new products in their formularies. Some have also entered into outcomes-based contracts with pharmaceutical companies. Such systems will force pharmaceutical companies to dramatically adjust their business models from simply selling medicines to managing outcomes and justifying costs. Doing so will require increased cooperation with the broader healthcare community throughout government, academia, hospitals, technology providers and so on to build health management infrastructure and access data. In short, traditional business models are under huge pressure, and pharmaceutical companies will have to work much harder to earn profits going forward.

Meanwhile, market growth is shifting toward emerging markets in Asia, Latin America and elsewhere, where pharmaceutical sales are forecasted to expand at double digit rates. Further reforms of legislative systems, especially regarding patent protection and enforcement, as well as improving regulatory conditions, will make these markets increasingly attractive for U.S. industry. Despite their impressive potential, developing countries pose immense challenges and risks for companies. To succeed, companies must choose markets selectively and devise tailored sales, marketing, acquisition and pricing strategies. Developed and developing markets often vary politically, culturally, socially and religiously in ways that effect pharmaceutical sales. They may vary, for example, in their use of traditional medicines or in the disease profile of the population due to different ethnic origins, diets and environments. Developing countries also possess very different economic attributes in terms of size, healthcare infrastructure, distribution chains and so forth.

Adding to the complexity, companies must overcome a range of regulatory hurdles that differ greatly by country and type of product. A lack of transparency and capacity within regulatory systems, as well as weak or ineffectively enforced IP laws, are all too common. Importantly, emerging markets differ from each other in their ability and political willingness to pay for innovative drugs. Consumers typically have to fund a larger share of their own healthcare costs as per capita government expenditure on healthcare is low. On average, low-income countries spend 4 to 6 percent of GDP on healthcare, compared to more than 10 percent of GDP for high-income countries, and current global economic uncertainties are likely to slow healthcare spending in the developing world in the near-term. Although growing pockets of wealthy patients willing to pay for high cost drugs provide opportunities for pharmaceutical companies, it will take decades before even the most promising emerging markets can afford the latest treatments and prices prevalent in rich countries on a widespread basis. Unsurprisingly, spending on cheaper, generic drugs is driving, and will continue to drive, most of the growth in emerging markets over the coming decade. While this bodes well for generics manufacturers, companies are not immune from increased price controls and other sales constraints imposed in these markets, which are already impacting revenues. Moreover, companies will face increased competition from local manufacturers as well as a variety of trade barriers, as governments seek to promote domestic industries. The pharmaceutical sector is

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often targeted by protectionist or industrial policies as governments around the world view it as strategically important. The industry is non-cyclical, generally employs individuals at above average incomes and ensures supplies of medicines to local populations.

Pharmaceutical companies entering a foreign market face a plethora of challenges. Not only does each country have unique regulatory, marketing and reimbursement environments, but foreign government policies and practices can pose impediments to market expansion, The most commonly cited problems include regulatory review processes that are non-transparent; lack of effective protection and enforcement for intellectual property rights, which result in widespread sales of counterfeit medicines; burdensome reimbursement and pricing policies; and high tariffs.

The following list elaborates on some, but not all, of the main issues facing pharmaceutical companies: Differences in regulatory approval requirements can lead to duplicative testing and clinical trial requirements, delays in product approval and higher costs to manufacturers. Many regulatory agencies lack adequate training and resources to review submissions in a timely and consistent manner, creating enormous backlogs, approval uncertainty and market access delays. There may also be concerns related to the security and maintenance of confidential business information (CBJ), such as clinical data that must be submitted for approval. Others include patent approval, patentability, data supplementation in patent applications, patent enforcement, compulsory licensing, regulatory data protection, pricing, localization (some trading partners, in an effort to protect or develop their own domestic industry limit or ban certain imported pharmaceuticals), tariffs, and counterfeits.

The following is a summary of the U.S. Market: Population - 322 million; Population over the age of 65 – 48 million (15%); Total healthcare expenditure - US$3.12 trillion (17.4% of GDP); Government healthcare expenditure - US$1.49 trillion (47% of total); Private healthcare expenditure - US$1.63 trillion (52% of total); Total pharmaceutical sales - US$333 billion (1.9% of GDP, 10.7% of total healthcare expenditure); Per capita pharmaceutical sales - US$1,036; Generic sales - US$70 billion (21% of total sales); Patented sales - US$244 billion (70% of total sales); OTC sales - US$19 billion (6% of total sales).

Fight the Fakes (cont.)...

themselves off as something they are not, fake medicines put people at risk, contribute to resistance of genuine treatments and undermine confidence in health systems. Fight the Fakes arose out of consensus among partner organizations: a coordinated multi-stakeholder approach, supporting the actions of the World Health Organization (WHO) and national governments, is vital to ensure this problem is properly tackled.

In its first three years, the campaign has participated in events and workshops across the globe, produced educational materials, held media briefings for young and seasoned journalists, and worked to collect and share the stories of people who have been impacted by fake medicines worldwide. Tapping into their respective networks, Fight the Fakes partners have the potential to share these resources and testimonials with millions of doctors, nurses, pharmacists, students and people working throughout the medicines supply chain, so that all are better equipped to combat this threat.

"Protecting the security of the pharmaceutical supply chains in the markets in which they operate - and ensuring the integrity of products within them - is a core competency of IFPW's members and a responsibility they take very seriously", says IFPW Foundation chair Eric Zwisler. "As such, IFPW is honored to serve as the next secretariat and to continue the good work of IFPMA and the other campaign partners to keep Fight the Fakes' momentum and to continue to raise awareness on such an important issue."

"Fake medicines are a global problem and it is only through global collaboration and dialogue that we will be able to fight together to address it and protect future patients and the general public from harm", added IFPW Executive VP and General Manager Chris Goetz.

"We are very pleased to have worked so closely with the Fight the Fakes secretariat these years, amplifying our ability to reach people with life-saving information," says Quentin Duteil, Project Manager at campaign partner the Fondation Chirac. "Building on our past joint initiatives at the World Health Assembly and workshops on regulatory system strengthening in Africa, our cooperation with IFPMA in fighting fake medicines will continue. With this transition, we welcome the unparalleled supply chain expertise of IFPW at the helm of Fight the Fakes, and we are certain the campaign will continue to grow with their guidance."

Participation in Fight the Fakes campaign is open to organizations involved in public health, already active in combating fake medicines or looking to become more engaged in raising awareness of the problem within their organizations as well as towards the public.

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operational performance and achieved financial results in line with or above our targets." said Chairman and CEO *Ari Bousbib*, "The post-merger integration is advancing well and we are pleased with the results."

- The **International Federation of Pharmaceutical Manufacturers and Associations** (IFPMA) has named *Thomas Cueni* to the position of Director General beginning February 1st, replacing *Eduardo Pisani*. A highly-respected member of the biopharmaceutical sector, he previously served as Secretary General of Interpharma and has worked closely with IFPMA during his tenure at Interpharma.
- Switzerland-based **Actelion** will be acquired by **Johnson & Johnson** for US$30 billion, or US$280 per share. The transaction was unanimously approved by both companies' board of directors. Actelion specializes in differentiated products for pulmonary arterial hypertension, which complements the portfolio of Johnson & Johnson subsidiary Janssen Pharmaceutical Co. Johnson & Johnson will retain Actelion's presence in Switzerland.
- **PharmaSmart International** has partnered with **McKesson Pharmacy Systems** on a new integrated solution for outcome-based patient management. PharmaSmart is a leading manufacturer of validated health screening kiosks and cloud-based health management solutions. The integration brings together PharmaSmart's clinical-grade, public use health kiosk solutions with McKesson's new *Clinical Programs Solution*.

(China Daily, Company Press Releases, Drug Store News, PharmaTimes, and Yahoo)