

Generic Drugs in the US Saved US\$227 Billion in 2015

*(Sources: QuintilesIMS, Generic Pharmaceutical Association
and Drug Store News)*

QuintilesIMS released its *2016 Generic Drug Savings and Access in the United States Report*, which it compiled on behalf of the Generic Pharmaceutical Association (GPhA). The report found that in 2015, generic drugs brought patients and the U.S. healthcare system US\$227 billion in savings, bringing the savings since 2005 from generics to US\$1.46 trillion. Generics saved Medicare (Federal program for the elderly) about US\$67.6 billion in 2015 (about US\$1,737 per enrollee) and Medicaid (federal & state program for the poor) had savings of US\$450 per enrollee, totaling US\$32.7 billion. “Generic drugs are the foundation of any successful effort to lower health spending and increase patient access to affordable medicine,” GPhA president and CEO Chip Davis said. “A diverse group of experts — the federal government, pharmacy benefit managers, consumer groups and others — agree that generic drugs drive system savings, not costs.”

The savings that the report highlights are particularly impactful in certain therapy areas and among certain patient groups. Mental health in particular saw US\$34.4 billion in savings, the most of any therapy area, and nearly US\$10 billion more savings than the second-ranked area, hypertension, which saw US\$25.8 billion in savings in 2015. Adults 40-65 years old see 45% of the generics savings, with seniors 65 years and older seeing 34% of the savings. Young adults 20-29 saw 14% of the total savings, and children 0-19 years old saw 7% of the savings.

The QuintilesIMS Institute report also highlights the fact that though generics make up 89% of prescriptions, they only constitute 27% of total medicine spending, implying that branded drugs making up 11% of prescriptions are responsible for 73% of costs — with specialty drugs making up 1% of prescriptions and 30% of total drug spending. With respect to biosimilars, the less costly alternatives to biologic treatments, estimates of the savings they could bring vary widely. The report said that estimates put potential savings between US\$44 billion and US\$250 billion over 10 years. Davis said in a conference call that because biosimilars are still in a nascent stage in the United States, time is needed to see what sort of competition and savings will emerge as more biosimilars enter the market.

In the immediate term, though, Davis said that the biggest area that GPhA and its Biosimilars Council are focusing on is ensuring the creation of policies that allow generics savings to continue and increase. “More can be done to increase patient access to safe, effective and more affordable generic medicines. GPhA will continue working with policymakers, regulators and others to bring greater health savings to our country,” Davis said. “That effort begins with policy that builds on this industry’s record of significant savings and promotes generic competition.”

In Brief . . .

- ◆ **McKesson Corporation** reported revenues of US\$50 billion for its 2nd quarter, up 2% year over year. Second quarter GAAP earnings per diluted share from continuing operations were down 49% year over year.

- ◆ **Walgreens Boots Alliance** announced its 4th quarter and FY2016 results, beating its own guidance. Fourth quarter net earnings attributable to Walgreens Boots Alliance determined in accordance with GAAP were US\$1.0 billion as compared with US\$26 million in the same quarter a year ago. Sales in the 4th quarter rose 0.4 percent year over year, or 2.5% on a constant currency basis. Fiscal year net earnings decreased 1.1 percent to US\$4.2 billion, reflecting fluctuations in the fair value adjustments of the company’s AmerisourceBergen warrants and the prior year gain on the previously held equity interest in Alliance Boots, which was largely offset by increased operating income. The company also announced an extension of the merger agreement between Walgreens Boots Alliance and Rite Aid Corporation to 27 January 2017.

- ◆ **Upsher-Smith Laboratories** has acquired 20 U.S. generic products from **Sandoz**, in a cash deal, contingent on product sales. Transaction terms were not disclosed. Included are 19 solid oral dosage products and one nasal product, which have all received approval from the U.S. FDA. According to IMS data, annual product sales for the products is approximately US\$400 million for the 12 months ended July 2016.

- ◆ **Novartis** announced 3rd quarter net sales of US\$12.1 billion with volume growth of 5% (offset by negative impact of generic competition and pricing.) Growth products contributed 36% of net sales (US\$4.3 billion) up 20% year over year. Net income was US\$1.9 billion, which was more than operating income due to higher income from associated companies.

- ◆ A grant from **The AmerisourceBergen Foundation** in the amount of US\$250,000 was awarded to Haiti’s largest non-government healthcare provider, Partners in Health, to build a new medical distribution center outside Port Au Prince. “Like AmerisourceBergen, the AmerisourceBergen Foundation is dedicated to support efficient and safe access to pharmaceutical care around the globe,” said *Gina Clark*, Executive Vice President of the AmerisourceBergen Foundation and Chief Marketing Officer at AmerisourceBergen. “With the financial support of this grant, PIH’s plans for a new distribution facility will go a long way towards accomplishing this goal in Haiti.”

- ◆ The **United Nations Foundation’s** 2016 Global Leadership Awards Dinner honored **Walgreens Boots Alliance** for its commitment to the UN’s Sustainable Development Goals through its support for well-being around the world. The award recognizes, in part, the accomplishments of Walgreens highly successful *Get a Shot. Give a Shot.*® initiative, which provides life-saving vaccines to children in developing countries through the

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Declining Sales of Gilead's Products Impacting Leading Japanese Wholesalers

(Source: Pharma Japan)

Drug wholesalers in Japan are braced for bleak earnings for FY2016 as they see dwindling revenues from Gilead Sciences' hepatitis C medication, *Harvoni*, with No. 1 distributor Suzuken's *Harvoni* sales in July tumbling as much as 70% from the peak month of December.

According to wholesale officials, wholesalers' revenues from Gilead's *Sovaldi* and *Harvoni*, launched correspondingly on May 25 and September 1 last year, hit the peak in October and December, respectively. Their sales declined after those months, and virtually leveled off between May and July this year.

Suzuken and Toho Holdings are the only primary distributors for Gilead drugs among the four major wholesalers in Japan. With these recent sales trends, the two firms' bearish projections for lower group sales for FY2016 (April 2016 – March 2017) have now become more convincing. In its earnings briefing in May, Toho forecast its sales of Gilead products in FY2016 at 80 billion yen (US\$696.8 million), down 20% from the prior year. According to a spokesperson, Toho had sales of 28.2 billion yen (US\$245.6 million) from Gilead products in April-July, and if this pace continues, the annual sales would end in line with the company's projection.

Meanwhile, Suzuken said at its earnings conference in May that its hepatitis C drug sales in FY2016 would plunge 70% to 50 billion yen (US\$43.5 million), and according to a spokesperson, it logged 43.6 billion yen (US\$379.8) from Gilead products in April-July. The quarterly figure suggests that the company apparently played it safe with its yearly outlook.

With the Gilead surge tapering off, the two wholesalers are looking to Ono Pharmaceutical's *Opdivo* to take its place. *Opdivo*, initially approved for melanoma, obtained the Japanese regulator approval in December for the treatment of unresectable advanced or relapsed non-small cell lung cancer (NSCLC). According to the officials, *Opdivo* brought in 32.6 billion yen (US\$284 million) for wholesalers in April through July, and if the drug remains on track, it would achieve Ono's annual sales forecast of 126 billion yen (US\$1.1 billion) in FY2016, making it a good candidate for the top selling product in Japan.

With *Opdivo*, however, Suzuken and Toho are not the only distributors among the four majors. According to wholesaler officials, the value-based market share of *Opdivo* sales in April-through July stood at 22.6% for Medipal Holdings, 21.0% for Suzuken, 20.9% for Toho, and 14.3% for Alfresa Holdings.

Furthermore, pressure on delivery prices is increasing as wholesaler customer dispensing pharmacies face tougher requirements for reimbursement fees following the fee revision in April. In April through June, all 13 major dispensing pharmacy chains suffered deteriorating operating profits. "There are pharmacies that don't even accept our final proposal on delivery prices," an official of a major wholesaler lamented. As wholesalers are scheduled to announce half year earnings in early November, Pharma Japan is predicting that the industry is likely to witness gloomy figures regardless of their offering of Gilead products.

Even though there has been a sales decline in Gilead products, Gilead is introducing a market expansion program through awareness-raising campaigns and collaborations with distributors.

Gilead expects some 100,000 patients to start treatments with Direct Acting Antivirals (DAAs) in Japan in 2016. However, with the initial demands tailing off for *Sovaldi* and *Harvoni*, the company is ramping up its efforts to find potential patients, with the aim of bringing 210,000 patients onto DAA treatments by 2019.

At a press conference on October 12, Gilead's Japan president revealed that the drug maker estimates the number of hepatitis C patients (HC carriers) in Japan at 800,000. Of this, 600,000, or over 70%, have been diagnosed, of whom 240,000, or 40%, are already on treatment by specialists. Of the 800,000 population, the company is now targeting undiagnosed patients, those not on specialist treatment, and those who are treated by specialists but not with DAAs.

The company is now boosting its commercials to raise awareness about the diseases among the general public. The company is to increase its detailing activities at medical institutions in cooperation with wholesaler partners. "We welcome a collaboration," a sales rep of a major wholesaler handling Gilead products told Jiho – the publisher of Japan Pharma. "Rival medicines will soon hit the market, so Gilead probably has many ideas (to compete with them)," the sales rep said.

In Brief (cont.) . . .

Foundation's *Shot@Life* campaign. Walgreens Boots Alliance's Co-Chief Operating Officer (and IFPW Director) *Ornella Barra* accepted the Global Leadership Award on behalf of the company.

- ◆ **Teva** and **Celltrion** have announced an exclusive partnership to commercialize Celltrion's biosimilar candidates in the U.S. and Canada. Under the agreement Teva will pay US\$160 million in an upfront payment and will be responsible for all U.S. and Canadian commercial activities, pending regulatory approval. Celltrion will be responsible for the completion of clinical development and regulatory activities.

- ◆ Irish drug manufacturer **Allergan** has announced that it has obtained global rights for the development and commercialization of experimental drug *MEDI2070* from **AstraZeneca Plc** in an upfront payment of US\$250 million. The drug is under development for the treatment of Crohn's disease and ulcerative colitis. The deal comes on the heels of a string of acquisitions announced by Allergan last month, including **Akarma Therapeutics**, **Tobira Therapeutics** and **RetroSense Therapeutics**. The company also successfully completed its tender offer to purchase all outstanding shares of Vitae Pharmaceuticals, Inc.

- ◆ Australia's **Foreign Investment Review Board** has approved the takeover of **Vitaco** by **Shanghai Pharma** and **Primavera Capital**. The deal is worth more than US\$235 million.

- ◆ U.K. health minister, *David Mowat* has announced the slashing of the community pharmacy budget by 4 percent. with further reductions of 3.4 percent in 2017-2018, in a speech to the House of Commons. The move comes following a big rise in overall pharmacy spend over the last ten years. Mowat stated "every penny saved by this re-set will be reinvested and reallocated back into our NHS to ensure the very best patient care."

(Chain Drug Review, China Daily, Drug Store News, Ethical Corporation, PharmaTimes, PR Newswire, Zacks Equity Research)