FOCUS

Vol. 24, No. 10 International Federation of Pharmaceutical Wholesalers May 18, 2017

IFPW Service Member Spotlight

Porzio Life Sciences Services

Porzio Life Sciences (PorzioLS) is a single member limited-liability company and a wholly-owned subsidiary of the law firm of Porzio, Bromberg & Newman, P.C. (Porzio), a law firm nationally recognized for its litigation and regulatory compliance work for the life sciences industry. Porzio has provided counseling services to the life sciences industry for over 30 years. PorzioLS provides non-legal services relating to the pre-approval, launch and commercialization of prescription drugs and medical devices. Together, the companies provide regulatory compliance and legal and business services related to product development, the Prescription Drug Marketing Act (PDMA), anti-kickback statutes, the Sunshine Act, FDA regulations, false claims act, global industry codes and OIG guidances.

PorzioLS helps pharmaceutical, medical device and biotechnology companies satisfy federal, state and global marketing and sales obligations. Additional areas of expertise include healthcare compliance program development, product commercialization, training programs, promotional/medical communications review, fraud and abuse, HCP contracting and interactions, internal investigations, compliance assessments and audits, monitoring support, distribution and licensing, and Sunshine Act, state and global transparency. PorzioLS also offers a varied portfolio of compliance tools and services related to the individual laws of the 50 states, the District of Columbia and the federal government, and transparency services pursuant to reporting requirements in almost 40 jurisdictions. The non-traditional combination of Porzio's legal services and PorzioLS' non-legal counseling and solutions allows for greater flexibility and range of services for our clients and customers.

Global Capabilities...Through our joint venture partnership with MedPro Systems, Porzio AggregateSpendID® was launched in July 2010. This best-in-class aggregate spend solution allows life sciences companies to capture, review, track and report interactions with U.S.-based HCPs and HCOs. As global regulations and reporting requirements have evolved in recent years, so too have the PorzioLS products and services, in order to keep up with the demanding regulatory environment.

PorzioLS leveraged its extensive regulatory and operations experience related to U.S. transparency and Sunshine Act requirements into global solutions as well. Porzio GST® is a true "end-to-end," fully hosted, web-based HCP management and transparency reporting tool that allows life sciences companies to capture, review, track and report interactions with European, Australian and Japanese HCPs and HCOs. PorzioLS has provided

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In Brief...

- **AmerisourceBergen Corporation** reported second quarter 2017 results with revenues of US$37.1 billion, a 4% increase year over year. Gross profits rose 16.8% from the same period last year to US$1.3 billion. Separately AmerisourceBergen has signed a new five-year pharmaceutical agreement with Express Scripts. The current agreement expires in September of 2017, while the new agreement will extend through September 30, 2022. "We are extremely pleased and proud to continue to be the strategic partner of choice and provide brand pharmaceuticals for Express Scripts," AmerisourceBergen's Chairman, President and CEO, *Steve Collis*, said. AmerisourceBergen's 2016 revenue contribution from its Express Scripts relationship was approximately US$23 billion.
- **Cardinal Health's** board of directors has approved a 3% increase to its quarterly dividend beginning July 15, 2017. The dividend increase (US$0.4624 per share) allows Cardinal to provide approximately a 2.5% dividend yield based on its current price.
- **McKesson Corporation** subsidiary **McKesson Canada** has announced significant upgrades and enhancements to its *PACMED Core* software platform. This platform is designed to support customers, improve efficiency of compliance packaging for patients, advance packaging accuracy and further enhance pharmacy workflow. McKesson Canada is the exclusive distributor of *PACMED* and *PACVision* to Canadian hospital and retail pharmacies.
- **Profarma** announced first quarter results for 2017, with consolidated gross revenues of R$1.2 billion (US$324.5

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IFPW Hosts Another Successful CEO Roundtable

Fifty-two international pharma executives attended the IFPW 2017 CEO Roundtable at the Corinthian Hotel in London last week. Attendees heard a variety of presentations on current topics of interest and thought-provoking ideas to be considered for future business strategy. The meeting kicked off with a fascinating in depth global overview of the pharma industry by QuintilesIMS' Doug Long and Per Troein, followed by a very candid perspective on Specialty and Biosimilars by Tony Hooper with Amgen. These were followed by a presentation on innovative end-user patient/pharmacy technologies by MedAvail Technologies, Inc. .Ari Boushib, CEO of QuintilesIMS, then concluded the morning session with an intriguing perspective on the role of informatics in healthcare outcomes.

The afternoon session kicked off with an overview of the U.S Health System and its complexities by Dr. Bede Broome with McKinsey. The next session, led by Eric Percher with Barclays, provided an overview of the Wall Street perspective of

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WHO to begin Pilot Prequalification of Biosimilars

(Source: Simeon Bennett, WHO Department of Communications)

This year the World Health Organization (WHO) will launch a pilot project for prequalifying biosimilar medicines, a step towards making some of the most expensive treatments for cancer more widely available in low and middle-income countries.

In September, WHO will invite manufacturers to submit applications for prequalification of biosimilar versions of two products in the WHO Essential Medicines List: *rituximab* (used principally to treat nonHodgkin's lymphoma and chronic lymphocytic leukemia), and *trastuzumab* (used to treat breast cancer). The decision comes after a two-day meeting in Geneva between WHO, national regulators, pharmaceutical industry groups, patient and civil society groups, payers and policymakers to discuss ways to increase access to biotherapeutic medicines.

If the WHO finds that the biosimilars submitted for prequalification are comparable to originator products in terms of quality, safety and efficacy, the medicines will be listed by WHO and become eligible for procurement by United Nations agencies who are heavily relied upon by many low and middle-income countries.

WHO will also review its 2009 Guidelines on the evaluation of similar biotherapeutic products to ensure that WHO's guidance to national regulatory authorities reflects recent evidence and experience. "Biosimilars could be gamechangers for access to medicines for certain complex conditions," said Dr. Suzanne Hill, WHO's Director of Essential Medicines and Health Products. "But they need to be regulated appropriately to ensure therapeutic value and patient safety."

Increased use of biosimilars, according to WHO, will also require patients and their physicians to understand and trust that the benefits of this type of medicine substantially outweigh any risks. WHO will be looking to countries with positive experience of biosimilars and partners for support in educating prescribers and patients on the benefits of these medicines and in advocating for greater awareness of biosimilars.

WHO will also advocate for fairer prices for all biotherapeutics to ensure that these treatments can truly benefit public health. This will include support to countries to develop price setting strategies that foster sustainable markets to deliver treatments to patients.

2016 Medicine Spending in the U.S. & Outlook Through 2021

(Source: Edited excerpts from a QuintilesIMS Institute Report authored by Murray Aitkens)

In the report, "spending on medicines" and "invoice-price spending" refer to the amounts paid to distributors by their pharmacy or hospital customers. It does not relate directly to either the out-of-pocket costs paid by a patient, except where noted, nor does it refer to the amount health plans or Medicare pay for medicines, and does not include mark-ups and additional costs associated with dispensing or other services associated with medicines reaching patients. "Net-price spending" is a proprietary derived estimate of the amount received by pharmaceutical manufacturers after rebates, off-invoice discounts and other price concessions have been made by manufacturers to distributors, health plans and intermediaries.

Spending on medicines in the U.S. increased by 5.8% to US$450 billion in 2016, growing at less than half the rate seen in the last two years, based on invoice prices. After adjusting for estimated rebates and other price concessions by manufacturers, which continued to rise in 2016, net spending was US$323 billion, up 4.8% over 2015 levels. When adjusted for these concessions, as well as economic and population growth, medicine spending increased 2.6% in 2016 and has increased by an average of 1.1% per year since 2006, while the balance of medicines being used has shifted strongly to specialty medicines from traditional treatments.

The average net price for brands already in the market is estimated to have increased by 3.5% in 2016, up from 2.5% in 2015, while remaining significantly lower than prior years. This reflects the heightened competition among manufacturers and more aggressive efforts by health plans and pharmacy benefit managers to limit price growth. Invoice price levels, prior to the impact of concessions, increased 9.2% in 2016.

Over 50% of positive spending growth in 2016 was from new brands that have been available for less than 24 months. Patients are seeking and receiving new treatments for cancer, autoimmune diseases, HIV, diabetes and other chronic conditions, driving US$17.4 billion of new spending growth on an invoice price level, and an estimated US$13.9 billion on a net basis, slightly lower than in the prior year but still significantly higher than historical levels.

Spending on all generic medicines declined slightly in 2016 as the spike in price increases of older generics seen in 2013 and 2014 is no longer driving growth in 2016. Total prescriptions dispensed in 2016 reached 4,453 million, an increase of 1.9% (compared to increases of about 2 percent seen in earlier years.)

The rising use of deductible plans, where patient copay is based on list prices, meant that 14% of brand prescriptions in commercial plans were paid during a deductible phase while those copays accounted for 39% of total brand out-of-pocket costs for patients in those plans. Many patients are abandoning prescriptions at the pharmacy due to "sticker shock" and abandonment rates for brands are 2.5 times higher when a patient faces a deductible and sees the full cost of the medicine compared to patients who had a set copayment.

Outlook to 2021: The outlook for U.S. spending growth on medicines has been revised significantly downward as a result of weaker than expected new product spending and a slowing of invoice price increases for branded products. Average growth was projected in the 6-9% range prior to the autumn of 2016 but projections have been revised down to 4-7% through 2021. Price increases for branded products existing in the market were projected to continue historic growth in the 8-11% range but are now expected to grow more slowly at 7-10% on an invoice basis, while the outlook for net growth is unchanged at 2-5% as pricing remains under intense competitive and payer pressure. The prospects for further innovative medicines becoming available over the next five years remain very bright despite a relatively small number of launches in 2016. The late phase pipeline holds 2,346 novel products and 40-45 New Active Substances are expected to be launched on average for each of the next five years. Oncology remains the area of greatest activity.

Spending is forecast to reach US$580-610 billion in 2021 on an invoice price basis, driven by innovation and offset by loss of exclusivity, including the impact of biosimilars. Spending on a net basis is expected to reach US$375-405 billion growing at a more modest 2-5% to 2021.

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EU, EFPIA and Australia transparency consulting and reporting services to the life sciences industry for over 4 years, and currently works with mid-size multi-national companies to support their European and EFPIA reporting obligations via Porzio GST. In addition to Porzio GST as a solution, PorzioLS provides global transparency counseling services to companies world-wide.

Another unique competitive advantage of PorzioLS is the International Life Sciences Transparency Database of the Porzio Compliance Digest (PCD) which provides subscribers easy-to-read excerpts and summaries of critical global information/updates on global reporting requirements concerning HCP/HCO transfers of value, anti-bribery and anti-corruption, and data privacy. The International Database includes international industry association codes of conduct and guidance documents and access to the International Life Sciences Transparency Compliance Module, providing an at-a-glance summary of the laws, codes, and pending legislation related to the aforementioned topics. International Database subscribers also receive access to the International InfoCenter News page, containing the latest global news, laws, industry codes and pending legislation impacting sales and marketing activities.

PorzioLS Licensing Services...One of the first services offered by PorzioLS was that of the acquisition and maintenance of distribution licenses. PorzioLS has developed efficient procedures that streamline the initial and renewal licensing process through its automated application forms, secure e-rooms for document delivery and sharing, established licensing agency contacts, and thorough knowledge of the diverse state licensing rules and prerequisites. PorzioLS has worked with over 250 life sciences companies, including preparation of over 4,000 initial licenses and supporting documentation.

With experience in licensing projects with diverse scopes, business models and timelines, the Distribution Licensing Team assists manufacturers and distributors in many ways, including: identifying jurisdictional and federal requirements related to your business model; preparing, reviewing and filing of applications through all licensing bodies; tailoring applications to distribution models - trade product, device and sample distribution; and ensuring compliance with requisites and prerequisites, including bonding, fingerprinting, licenses to do business, and testing of designated personnel. The team is also in constant contact with state and federal licensing agencies, further assuring a timely application process.

PorzioLS and Porzio often assist companies in a consulting or legal capacity, respectively, with distribution and state licensing strategies. This is often done in conjunction with mergers, acquisitions, or restructuring by assessing the licensing and notification implications of a particular transaction and planning to assure uninterrupted supply. In addition, PorzioLS and Porzio consult on Drug Supply Chain Security Act issues impacting state licensing, as well as on the increasing number of county drug take back programs. Porzio often performs licensing gap analyses for companies with multiple facilities and complex distribution models and assists in notifications to the various boards that may be required outside of a licensing renewal.

PorzioLS and the Porzio family of companies offer innovative services that are unique within the life sciences industry with a team of compliance and consulting experts who understand the issues and complexities of operating and expanding companies of every size and stage of the development spectrum. PorzioLS and Porzio's goal is to partner with our customers to fully understand their business needs and help them achieve their ultimate goals.

For more information, please contact Frank Fazio, RPh, JD, Vice President of Distribution and Licensing Services, at Fazio@PorzioLS.com, or visit www.PorzioLS.com.

IFPW's New Service Member Spotlight Feature - With this issue of the FOCUS Newsletter, IFPW will begin featuring one of its Service Member companies every two months with the goal of highlighting each company's background, history and considerable service offerings. We hope that you will find this information useful and timely as you make decisions for your company.

In Brief (cont.)...

million), highlighted by a 56.7% rise in its retail sales division. The gross profit for its pharmaceutical distribution division rose by 9.3% to R$82.4 million (US$22.2 million) and its independent customer segment grew by 19.9%. Its specialty division also saw an increase in sales, by 12.8%.

- **Walgreens** and **Rite Aid** have taken steps to force antitrust officials at the U.S. Federal Trade Commission to make a decision on the Walgreens' merger with Rite Aid. Both companies have said that they have complied with all requests for information by the FTC and have called for a deadline of July 8th for the agency to make its final decision.
- The **National Association of Chain Drug Stores** (NACDS) and the **Healthcare Distribution Alliance** (HDA) submitted a joint op-ed that was published in *The Hill* concerning the importation of drugs to the U.S. from foreign markets, and the risks associated with these imports. *John Gray*, President of HDA, along with NACDS president, *Steve Anderson*, reiterated that the importation of foreign market pharmaceuticals is not a health cost panacea and would, in fact, undo current legislation designed to maintain the integrity of the closed pharmaceutical supply chain in the country.

(Sources: Company Press Releases, Drug Store News, Drug Channels, FiercePharma)

CEO Roundtable (cont.)...

the pharmaceutical wholesale/distribution market. The meeting wrapped up with a presentation by Todd Skrinar of Ernst & Young, who has considerable experience with clients in the pharma distribution space, on the use of digital technologies in the world healthcare market today.

IFPW Chairman Steve Collis summarized the work of IFPW Foundation and challenged members to become more involved and support its activities, including the partnership with Gavi Alliance and the Fight the Fakes campaign (against falsified medicines.)

The feedback by attendees was nothing short of amazing as this meeting truly allows networking at the highest level within the member organizations. Companies representing Argentina, Australia, Belgium, Canada, China, Finland, Japan, Mexico, Peru, Russia, Singapore, South Africa, Sweden, Switzerland, United Kingdom and the U.S. were all in attendance. If you were not able to attend this year's meeting be sure and make plans to attend the IFPW 2018 CEO Roundtable which will be held in New York City April 9-10, 2018.