FOCUS

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IFPW Begins Membership Visitation Program

In an effort to keep abreast of local market changes and fully understand members' needs and businesses, IFPW has launched a membership visitation program under which it will attempt to visit each of its members at least once over the 2017-18 period, and at members' own facilities/headquarters whenever possible. During these visits, feedback on IFPW's programs and service offerings will also be solicited to maximize the value companies derive from their membership and to shape future offerings and programming.

An inaugural visit was made on March 9th to 2 Wholesaler members in Mexico City, Nadro S.A. and Fármacos Nacionales S.A.. We thank these members for their time and hospitality and special thanks to the Mexican wholesalers association – DIPROFAR – for its support of these visits and their organization!

More on Mexico - *Did You Know?*

1. The Mexican market has decreased in value from approximately US$15 billion to US$13 billion, in US dollar terms, over the past 5-6 years despite experiencing steady moderate growth over the same period in local currency terms.

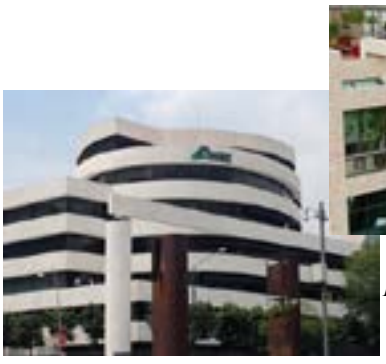
2. The Manufacturer-Wholesaler relationship continues to evolve with more Fee-for-Service models being introduced and adopted.

3. Significant changes are occurring within the Retail / Retail Pharmacy market. Namely, large national pharmacy chains are outpacing others' growth using a strategy of co-locating low-cost prescribing doctors / medical consultancies within their stores and offering private-brand generics.

4. Retail consolidation, to 4 larger players, has led some manufacturers to bypass the Wholesale channel and increasingly sell direct. This is beginning to negatively affect both service levels in the direct sales and distributors' market shares.

5. Mexico was historically a brand-dominated pharmaceutical market but generics have recently increased in share and grown rapidly in a variety of forms, resulting in new distribution and retail models for these products.

6. In addition to manufacturers producing private-label brands for retailers they are also increasingly offering their own brands and branded generic products.



Corporate Headquarters of Fármacos Nacionales (above) and Nadro S.A de C.V. (left)

In Brief...

- The **Innovation Network Corporation of Japan** (INCJ) has partnered with **Takeda Pharmaceuticals** and wholesaler **Medipal Holdings** to form a biotech venture valued at ¥10 billion (US$88.25 million). The new company will be named **Scohia Pharma** and is slated to launch its operations on April 1, 2017. The joint company will be located in Takeda's Shonan Research Center in Fujisawa. Each company will own an equity stake in the company, with majority ownership by the INCJ (70.5%.) Takeda's and Medipal's stake will be 19.5% and 10% respectively. The new company will initially focus on renal, metabolic and cardiovascular areas, but will work to expand to other areas in the future.
- U.S. wholesaler **Cardinal Health** has been recognized by the **National Association for Female Executives** (NAFE) as one of the nation's best workplaces for female advancement. Cardinal's employee resource groups, mentoring programs, sponsorship and leadership programs, and its co-ed speakers' bureau were specifically highlighted. This is the sixth consecutive year that Cardinal Health was listed among the NAFE Top 60 Companies. Cardinal was also named the winner of the **Healthcare Distribution Alliance's** 2017 Distribution Management Award for its ergonomically friendly

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Can a Balance Among Value, Price & Accessibility be Achieved?

(Sources: Scrip, Drug Store News, Drug Channels, PharmaTimes and company press releases)

The pharmaceutical industry, which includes its supply & logistic chain, is facing a significant challenge: is a particular pharmaceutical therapy producing desired patient outcomes; is it an incremental or a transformational therapy; what is the value of that outcome (outcome/cost ratio) v. other degrees of therapeutic outcomes for the same patient; what does it cost – to include the component/chain costs - to achieve these outcomes; and, does the patient have access to these therapies in reference to therapy availability and/or cost of therapy? It is a complex equation with no simple solution. The ultimate target, of course, is the patient; however, the gateway to the patient is money; the cost of money and its sources: investments, taxes, insurance premiums and profits.

The focus of this article will be, for the most part, on the U.S. market. Nevertheless, every country is facing the "affordability dilemma"- how to provide affordable healthcare that is accessible to all and, at the same time, sustain innovation.

Investor's perspective: Let's begin with a few key points that were discussed among six biopharma and venture capital executives at a recent J.P. Morgan Executive Roundtable. The general theme of the discussion was the environment for financing

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Balance (cont.)...

innovative drugs and defining the healthcare value of new drugs from the perspective of patients, payers and partners. The general conclusion of the discussion was that even before delivering novel therapies to patients and winning reimbursement from payers, companies need to offer something valuable to potential collaborators or acquirers [the investor]; and the deal-making environment for such medicines, the executives agreed, is robust.

• In reference to oncology, precision medicine was going to be the next step forward in treating cancer but with the advent of immunotherapy it has become difficult to define precision medicines. The solutions are no longer simple. How does the industry move towards a value-base model when the model may be different for oncology, for pain management, for rare diseases, and other medical conditions?

• From an investor and CEO standpoint, the manufacturer determines if a new product is incremental in value or transformative. If it is going to be incremental and it is a product that fits in the pharma's portfolio, a company might be willing to take a product that will not demand a huge price, but will address the return on investment through volume. However, if a new product is a whole new therapeutic area and the company must build a support structure around the product, this would be classified as a transformation therapy, having a much higher risk.

Manufacturers' and Insurers' perspective: Merck and the insurance company, Aetna, have entered into a value-based agreement for Merck's Type 2 diabetes medications *Januvia* (sitagliptin) and *Janumet* (sitagliptin plus metformin). The contract will see Merck's rebates for the drugs based partly on their ability to help Aetna's commercial members with Type 2 diabetes achieve or maintain treatment goals. "At Aetna, we believe that focusing on how physicians prescribe medications in real-world settings is a key element in determining the value of the treatment," Aetna EVP and chief medical officer Dr. Harold Paz said. "It is in everyone's interest to ensure that patients receive appropriate medicines to help patients achieve their treatment goals."

"Merck shares Aetna's commitment to focusing on patients, and we are confident that the value-based agreement will help advance our common goal of helping patients with type 2 diabetes," Merck president U.S. market, Global Human Health Robert McMahon said. In a separate initiative, Merck will be the first healthcare company to participate in AetnaCare, a health and wellness initiative that provides members personalized knowledge, tools and support to be more proactive in managing their health. AetnaCare combines real-time identification of target populations, customized care maps that provide evidence-based actions for specific conditions and health ecosystem curation to bring together appropriate clinical and non-clinical services. Merck has used its insights and knowledge to create educational resources and tools to address patient engagement, behavior and adherence. The program will initially target patients with hypertension and diabetes in the mid-Atlantic markets. "Merck is pleased to collaborate with Aetna on this unique patient-centered approach to care by sharing our adherence and educational resources to help support the health and wellness of AetnaCare members," McMahon said.

Earlier this year, Cigna signed similar value-based agreement with Amgen for its *Repatha*, with Sanofi and Regeneron for their *Praluent*, both members of a potentially pricey new class of drugs that treat high cholesterol.

An example of a wholesaler's perspective: McKesson Health Solutions recently released a national study finding value-based reimbursement has firmly taken hold but that payers and providers are struggling to implement some of the fastest growing payment models. In response, McKesson Health Solutions announced it has expanded its portfolio to include ClarityQx, a value-based payment technology, through the acquisition of HealthQX. This technology enhances McKesson's ability to help customers rapidly and cost-effectively transition to value-based care by automating and scaling complex payment models, such as retrospective and prospective bundled payment.

Medical field's perspective: Medical experts in the US have called for valuebased pricing to curb 'outrageous' drug costs that are bankrupting' patients. Speakers at the Drug Pricing: Public Health Implications panel, presented by Harvard's T.H. Chan School of Public Health and Reuters, were in favor of stepping away from the country's current system, where pharma companies can set any price they choose. Dr. Lowell Schnipper, chairman of the American Society of Clinical Oncology's Value in Cancer Care Task Force, suggested that patients could only pay for drugs when they work, and that there should be a systematic way to determine the value of costly cancer drugs for patients. "I'm appalled at how many Americans are going into bankruptcy because of outrageous costs," he said. However, he also emphasized the importance of incentivizing pharma research. "As a doctor who treats patients I want new drugs. Some of these are nothing short of miraculous. We need to reward innovation in some way." Steven Pearson, president of the Institute for Clinical and Economic Review (ICER), an independent nonprofit group that evaluates clinical and cost effectiveness of drugs, added: "Americans at the same time are getting tremendously ripped off with drugs and also getting tremendous value and we almost never know when we're getting ripped off and when we're getting real value and that has to change."

Government's perspective: A focus on price control via reference pricing, value or outcome pricing, claw-backs, negotiated maximum accumulative costs, periodic pricing surveys, and others. In the U.S., the world's largest market, President Trump said he's working on a 'system' to reduce prices, promising to lower medicine costs for the American people. He said he's working on a "new system where there will be competition in the drug industry." An analyst at Credit Suisse, Vamil Divan, believes that the administration's continued focus is on drug pricing,

The President has promised to lower drug costs multiple times -- and threatened to use the government's buying power to force prices down -- but so far he has not unveiled any specifics about

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www.ifpwfoundation.org/PDF/2016 IFPW Foundation Annual Report.pdf

Balance (cont.)...

how to do so. He has alluded to a bidding process in the past. Unlike most countries in the world, the U.S. does not directly regulate medicine prices. Medicare Part D, the prescription drug part of the government program for the elderly, already includes multiple formulary tiers with branded drugs that are interchangeable, meaning they can generally compete against each other, another analyst wrote.

Lowering co-payments is a short-term possible way of lowering drug costs, according to Divan, the Credit Suisse analyst. He further wrote that he's unclear as to how Part D could be reformed since pharmacy benefit managers -- middlemen who negotiate drug prices in secret -- are already providing "some competition." There could be some potential changes to Part B policies, he said. President Trump is "committed to making drugs more affordable while promoting innovation, and cutting regulations to encourage drug companies to bring back operations and jobs to the United States," the White House said in an emailed statement.

In the meantime, President Trump has nominated Scott Gottlieb, M.D., to be the commissioner of the Food and Drug Administration (FDA). In addition to his role overseeing the FDA, Dr. Gottlieb will be a key policy advisor to the Trump administration on drug pricing, according to Dr. Adam Fein of Drug Channels. Dr. Gottlieb is very familiar with the current incentives in the gross-to-net bubble-the growing spread between a manufacturer's list price for a drug and the net price to a third-party payer after rebates. His solution is to migrate brand-name pricing from today's formulary rebates to up-front discounts. Such a shift, predicts Dr. Fein, would radically disrupt the business models and economics of pharmacy benefit managers (PBMs), wholesalers, and pharmacies.

Japan Ups the Ante on Drug Distribution after Fake *Harvoni* Issue

(Source: Pharma Japan)

The Ministry of Health, Labor and Welfare (MHLW) issued notifications on February16 urging wholesalers and pharmacies to thoroughly record and manage drugs they are handling, calling on prefectural authorities to carry out tightened compliance surveillance.

In the notifications, the MHLW spelled out that when wholesalers/pharmacies purchase a drug from new individuals/wholesalers, confirming their name and other data their wholesaling license numbers and contacts must be also confirmed and recorded. The ministry also specified that the persons in charge at wholesalers/pharmacies must confirm whether a supplied drug is unopened, package inserts are enclosed, or abnormalities exist, and if they find something suspicious, they must ask the supplier about the distribution background of this drug or how it has been managed.

The notifications asked prefectural authorities to ensure these rules will be followed by wholesalers/pharmacies in their jurisdictions. An official of the Ministry of Health, Labor and Welfare (MHLW) asked prefectural authorities on February 28 to carry out surprise inspections on wholesalers and pharmacies by the end of March in order to strengthen their compliance surveillance efforts.

"As a basic rule, we'd like you to conduct inspections without prior notice," Tomonori Izawa, director of the Compliance and Narcotics Division of the MHLW's Pharmaceutical Safety and Environmental Health Bureau, said at an annual meeting of prefectural officials in charge of pharmaceutical affairs.

In Brief (cont.) . . .

and timesaving upright refrigerated unit. This annual award was presented at HDA's Distribution Management Conference earlier this month in Palm Desert, CA.

- In an effort to boost its presence in China, German life sciences company **Bayer AG** is seeking business opportunities in healthcare and agriculture. In 2016, Bayer invested US$106.4 million to extend a pharmaceutical manufacturing plant in Beijing. *Celine Chew*, President of Bayer Group in China, stated "China is the third-largest market for Bayer globally and an important driver for growth of our business. The main business opportunities for Bayer in China are in areas that contribute to the nation's healthcare, agriculture, and better quality of life goals." These goals are outlined in the Health China 2030 Initiative, announced by China's President, *Xi Jinping*, in August.
- For FY2015, average R&D spending among (28) Japanese drugmakers surged ¥1.46 billion (US$12.9 million) year over year, to a total of ¥62.02 billion (US$54.9 million). **Takeda Pharmaceutical** topped the list at ¥338.2 billion (US$2.98 billion) followed by **Astellas Pharma** and **Daiichi Sankyo** at ¥225.67 billion (US$1.99 billion) and ¥208.66 billion (US$1.84 billion) respectively.
- **Alfresa Pharma** (Japan) has appointed *Koichi Shimade* as its next President of the pharmaceutical manufacturing unit, effective April 1. He will assume the position following *Kenichiro Iwaya*, who will remain a member of Alfresa's Board of Directors.

(Chicago Tribune, China Daily, Company Press Releases, Drug Store News, and Pharma Japan)