IFPW FOCUS IFPW

Vol. 23 No. 23 International Federation of Pharmaceutical Wholesalers December 1, 2016

National Association of Boards of Pharmacy® (NABP®) Introduces .Pharmacy Top-Level Domain Program

(NABP Press Release)

A .Pharmacy Top-Level Domain (TLD) Program has been developed by the US' National Association of Boards of Pharmacy (NABP) and a global coalition of stakeholders. The initiative is intended to simplify the process of safely buying medication online by allowing consumers to identify trusted online pharmacies and pharmacy-related websites (in a sea of rogue internet drug outlets) just by seeing ".pharmacy" in a URL/website address.The program is available to a wide range of pharmacy community members, including wholesale drug distributors, who can assure the public that they can have confidence in their products and services and that accountability is valued. Consumers can find safe online pharmacies at a glance. Unlike .com or .biz, which do not require a verification process, websites with a .pharmacy domain undergo initial and ongoing evaluations to ensure that they meet a set of safety standards.

In the past, trust seals (images) on websites showed users that they were visiting a credible website and receiving legitimate products or services. However, seals have been and can be easily faked by rogue websites; often the seals are simply copied and pasted. Out of more than 11,400 websites selling prescription drugs that have been reviewed by NABP, 96% were found to be operating illegally. With the low odds of finding a trusted website, a fraud-proof way to find safe pharmacy and pharmacy-related websites was needed.

NABP worked with international pharmacy regulators and organizations – such as the International Pharmaceutical Federation (FIP) – to make the task of finding safe online pharmacies and pharmacy-related websites as easy as looking at a URL. NABP launched the .pharmacy domain in 2014, and now applications from the United States, Canada, Great Britain, Hong Kong, Ireland, Spain, and Australia can be processed. NABP is also in discussions to process applications from a growing list of additional countries.

There is no way to fake a .pharmacy domain, as the website's address is the "seal." When one sees ".pharmacy" in a URL, it means that the website has been verified based on NABP's 10 core safety standards. Licensure, Prior Discipline, Legal Compliance, and Validity of Prescriptions are some of the standards that are evaluated.

This level of verification is the reason that Google, Yahoo!, and Bing have made .pharmacy websites automatically eligible for advertising through their search engines in the US and Canada and that Visa recognizes websites with a .pharmacy domain as legitimate pharmacy merchants. The .pharmacy domain cannot be resold or transferred once an organization or company purchases it, ensuring that the domain name remains with the approved domain name holder.

.Pharmacy is a response to the ever-changing online pharmacy landscape. It is important for legitimate pharmacy-related companies/organizations to be able to set their websites apart from fraudulent vendors that sell toxic, counterfeit medications or divert legitimate medicines, such as controlled substances that are sold without a prescription, to feed addictions. Furthermore, 88% of websites reviewed by NABP appear to have affiliations with rogue networks of internet drug outlets. These complex criminal rings pull revenues away from legitimate wholesale drug distributors and manufacturers, while harming unsuspecting consumers.

Whether a website is for an online pharmacy, a distributor of medications, or a regulatory agency, .pharmacy assures customers and consumers that they are receiving genuine products or information. NABP continues to work toward making the .Pharmacy TLD Program a truly global initiative that decreases the public health threat caused by rogue websites. To learn more, visit *www.safe.pharmacy*.

In Brief...

- **AmerisourceBergen Specialty Group** (ABSG) announced the construction of a 300,000-sq. ft. corporate campus in Carollton, Texas. The facility will serve as AmerisourceBergen Specialty Group's new regional headquarters. "AmerisourceBergen is the essential partner for pharmaceutical manufacturers and providers; we continue to rapidly grow our capabilities to help our partners to improve patients' lives," said *James Frary*, EVP, President of ABSG.
- **Celesio Group** announced first half revenue for 2017 (ended September 30th) of €10.4 billion (US$11 billion), a decrease of 2.8% year over year. Sales of the Norwegian and Swedish businesses, combined with exchange rate effects, had a negative impact, though partially offset by revenue growth in the German wholesale operation and acquisitions that were completed in the first half of 2017.
- **McKesson Canada** named *Paula Keays* president, effective immediately. Keays will oversee 4,000 employees and will be responsible for driving sales, marketing and operations for the business.
- **Cardinal Health** has purchased Navidea Biopharmaceuticals' **Lymphoseek**, an FDA-approved agent for lymphatic mapping in patients with solid tumors. Under the terms of the deal, Navidea will receive US$80 million at closing and up to US$230 million in milestones through 2026, with US$20.1 million guaranteed over the next three years. Cardinal will also license a portion of the intellectual property back to Navidea to allow it to develop and market new immunodiagnostic and immunotherapeutic products.
- **CVS Pharmacy**, the retail division of **CVS Health**, and **OptumRx**, **UnitedHealth Group's** freestanding pharmacy care services business, will join forces in order to provide greater convenience and value to customers. This new pharmacy network will offer eligible OptumRx members the ability to fill 90-day prescriptions at prices to equal to home delivery copays at nationwide CVS locations, as well as through OptumRx home delivery. It is expected that the combined entities will also increase consumer engagement, improve health outcomes and leverage

(continued on page 3)

Will Japan's Generic Era Drive Consolidation in the Wholesale Sector?

(Excerpts from a commentary article written by Takashi Ebisawa and published by Pharma Japan)

The author was struck by the news that newly launched generic versions of Eli Lilly's antipsychotic med *Zyprexa* (olanzapine) are being sold to dispensing pharmacies at an enormous 10% of the original drug's reimbursement prices. This is in addition to a fierce price war in the generic space; however, the author wonders if wholesalers can withstand the burden of distribution costs and outlays required even for lower priced products.In June, generic versions of *Zyprexa* joined the NHI price list in droves, which was immediately followed by their launches on the market. According to a change in generic pricing rules implemented in April, first oral generics are priced at 40% of their original drugs when more than 10 brands seek listing. For *Zyprexa*, 21 companies flocked to its generic market, making their products subject to the 40% rule, but their prices went even lower. For example, *Zyprexa* 5 mg carries an NHI price of 258.3 yen (US$2.26), while its generic versions have an NHI price of 83.5 yen (US$.73), which works out at 32% of the original drug price. The delivery prices of *Zyprexa* generics are even lower. "*Zyprexa* generics are sold to pharmacies at 10%-20% of the original drug prices because the competition between generic makers is so stiff," an official with a regional wholesaler told Jiho (Pharma Japan). Generic makers push for cheaper invoice prices, making it impossible for wholesalers to maintain their delivery prices, the official lamented. "While the prices of *Zyprexa* generics are going down to one-tenth of the original drug prices, distribution costs remain virtually the same," said the official, calling for urgent discussions on a new cost sharing scheme to secure sufficient margins for wholesalers so that they won't go under. The health ministry's *"Ryukaikon"* council for the improvement of ethical drug distributions compiled a proposal in September last year, calling for a new margin scheme for generics based on the actual amounts of distribution costs, instead of percentage based rebates that are usually applied to drug prices.

Another official with a smaller wholesaler also frets whether his company can survive in what is now widely called the "80% generic era," where the government would achieve a target generic use rate of 80% by the end of FY2020. With the demise of long-listed products, or off patent brand name drugs, wholesalers are now losing allowances from these products which were once their major revenue stream while they face the need to distribute rapidly increasing generics with lower price margins. Against this backdrop, this official is hoping for the Ryukaikon proposal to be implemented.

On the other hand, major wholesalers do not necessarily think the same way. One official with a major wholesaler said that their plan is to boost efficiency through high tech logistics centers, and if that's not enough to save costs, they would offer different services for branded drugs and generics, such as the frequency of deliveries. An official with another wholesale major also said that they would continue to set up high tech logistics hubs and hold down costs. Both officials did not even mention the new margin scheme. It appears that the major wholesalers are in a sense looking at the 80% generic era as a good opportunity to purchase smaller players in a broader industry shakeup.

US and European markets are 5 to 10 years ahead of Japan in terms of generic use rates, which stood at 92% in the US, and 73% in the UK, according to data released by the Japanese health ministry (annual average in October 2013 - September 2014). At IFPW's most recent General Membership meeting held in September, IMS' Doug Long reported that in the past five years generic related vertical mergers have been gaining momentum in the distribution industry of the US and Europe, citing as examples the launch of a generic sourcing joint venture between CVS and Cardinal Health and a partnership between Walgreens Boots Alliance and AmerisourceBergen. As a result of these moves, at least five wholesaling groups handle 90% of generics in the US, he noted. Japan has a healthcare system different from those in the US and Europe, but if these oversea s markets are any guide, there would be some kind of consolidation among the 75 member firms of the Federation of Japan Pharmaceutical Wholesalers Association (JPWA) as they prepare for the 80% generic era.

Glaxo CEO's View on the Industry's Future

(Source: edited excerpts from an article prepared by Sten Stovall and published by Scrip)

Glaxo's CEO Andrew Witty issued stark warnings at a recent industry conference on the need for far-reaching change within the industry. Addressing this year's FT Global Pharmaceutical and Biotechnology Conference in London on Nov. 16, Witty, who is retiring as the head of Britain's largest drug maker in 2017, began his keynote address on transformational strategies by saying the sector "is a super long life cycle industry - and if you haven't already started to think about how to deal with some of the challenges we saw coming 10 years ago, then it's almost certainly too late."

Witty added: "So if you continue to believe that R&D is a function of how much you spend rather than the efficiency or the cost per molecule of what you create then your time for fixing that strategy is diminishing rapidly." He said the old reliable fallbacks for inefficient pharma business strategies – price-oriented silo mentalities and selling expensive medicines into the once ravenous US healthcare market – are no longer viable. The world has radically changed and more is coming. Meanwhile the industry's productivity has plummeted.

"That's why we have these very high costs per molecule. To address that, you need to make very fundamental changes in the way you think about how you generate innovation, and you need to make very fundamental changes in the way in which you think about how you create returns for your organization." Witty said pharma in the past could mainly focus on a drug's launch price, but added "that's no longer the case. In fact, we shouldn't be looking at all at what the initial launch price is. We should be much more focused on what the returns are that that product can generate." In short, he said, the drug industry should move away from a fixation with price and orient its commercial strategies to focus on volume.

"It's inevitable that you have to move in that direction, because the driver of price-driven economics in this industry [the US market] is no longer capable of growing at the rate that it has historically grown," Witty stressed. "You need to think of a very different approach. How do you create more [patent] time? How do you create more [drug] volume? And how do you find a way to ensure that your products come through at the lowest possible cost and the highest possible quality, because the trap of being too low on cost is that you lose quality and that loses [patent] time and so the whole mix of drivers of return are inextricably combined," Witty said.

Going forward, the industry will see a merging of many of the trends which have been emerging over the past decade but which have been broadly under the surface. They are now seen globally. These include increasingly aggressive stances towards healthcare provision from government, HTAs (Health Technology Assessments) and payers, coinciding with increased focus on pa-

(continued on page 3)

IFPMA Holds 28th General Assembly

The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) held its 28th General Assembly this week in Washington, DC. Following an opening reception and dinner at the Italian Embassy, IFPW's Mark Parrish and Chris Goetz had the opportunity to participate in the event and network with the manufacturer colleagues in attendance as well as deepen IFPW's existing relationship with the IFPMA staff.

The Assembly's program consisted of 2 moderated discussions on the challenges and opportunities of "How do we ensure sustainable use of innovative medicines by patients in 2030?" which included participants from multiple stakeholder groups including academia, NGOs, the donor community, regulators and industry. In addition, there was a keynote address on neglected tropical diseases (NTDs) and vaccine development as well as remarks made by IFPMA's incoming and outgoing presidents. The recurring themes of the program centered around the challenges of NCDs, NTDs and access to medicines around the world - along with discussions on antimicrobial resistance (AMR), global health security and pandemic preparedness / response – in the context of the new Sustainable Development Goals (SDGs) and important roles industry will play in efforts to accomplish them.

Dr. Stefan Oschamann, CEO of German's Merck KgAA, completed his 2-year presidency of IFPMA and outlined the association's accomplishments and increased presence and relevance within the global health community. Ian Read, CEO of Pfizer, concluded the Assembly as IFPMA's incoming president. He shared his visions for the future and commitment to continue IFPMA's good work, stating, "The SDGs recognize that while there is still work to do to reduce the burden of infectious diseases we need to apply this same level of commitment, innovation and focus when it comes to the growing burden of non-communicable diseases. IFPMA has an important role to play and is well positioned to inform the development of public policies that promote solutions to address non-communicable diseases while simultaneously enabling health systems to address the barriers that are preventing access to quality care for everyone".

Both presidents recognized the leadership and accomplishments of IFPMA Director General Eduardo Pisani, thanking him for his commitment and hard work. Eduardo will be leaving IFPMA at the end of January. He has been a great friend and ally to IFPW so we wish him much success and happiness in the future!

Glaxo (cont.) . . .

tient outcomes. "They are reacting to an anxiety which is as deep in Detroit as in Mumbai about whether or not there will be access to medicine. And those trends, those tidal shifts are beginning to break through the surface," Witty said. "That's why it doesn't really matter too much who won the US election because the direction of travel is not determined by one stakeholder in the White House but by multiple stakeholders in public and private environments, and is already set: More control, more focus on lifetime cost, more aggressive willingness to intervene to control, and ultimately determine how health care evolves; more standardization, more protocol developed. We're already seeing that in Europe in different formats. And we'll start to see it in the rest of the world."

Witty emphasized the importance of diversifying risk profiles from a group's primary drug development: in the case of GSK the group's vaccines and consumer goods businesses have different risk cycles to that of pharma. "For us this allows us to think long-term about the smoothing out of return curves for our investors. That makes sense provided you're investing in the sector for the cycle time for that particular sector … as managers you have to develop a business so that it is in sync with its cycle time. And in the drug sector, you're talking decades for the life of a product, not years and certainly not months." He said the challenge for the industry "is whether we're clever enough to reinvent our commercial business models, both from a pricing view, our cost structures, and our go-to-market models to ensure that we are able to effectively migrate from an industry which has been far too price orientated in its determinants to one that is much more volume orientated." Consequently, the drug industry needs to get back to an equilibrium for aligning what the industry needs from a return point of view to drive its biology exploitation and what society needs from a cost point of view

"These pressures are going to get more intense and more worldwide. So, you need a strategy that allows you to exist in that world. We need to evolve our business models to be in step. We can no longer use the language from the 1990s of price and blockbusters." Instead, the concept of control mechanisms has become "a language" that the industry is now dealing with. "What our industry needs to do – whether it's large, medium or small – is move with that. You want the conversation to change into a return/cost dialogue and that increases the solution space; there is more to negotiate in order to get into that conversation - and it creates a much more interesting set of options for your corporate strategy, and a greater solution space," Witty said.

Everything was not doom and gloom, however. Witty did identify positive trends for the sector, not least the continued growth of the world population, and the prospect of more than 6 billion people moving into healthcare consumption for the first time; 300 million new healthcare consumers a year; 150 million babies a year born worldwide, the vast majority of them in emerging markets. "And every year will see a rising propensity to purchase, a rising demand, a rising aspiration and an increasing government interest for that aspiration," he said. Therefore, drug companies need to be capable of engaging with that volume, Witty concluded.

In Brief (cont.) . . .

the shared platform to deliver new pharmacy and health solutions to customers.

- **Omnicell** announced that it will acquire **Ateb**, as well as its Canadian affiliate **Ateb Canada** in a deal valued at US$41 million. The move will bring together the two companies in order to focus on medication adherence solutions through Ateb's *Time My Meds* medication synchronization tool and its pharmacy-based patient care solutions.
- German companies in China are hopeful that the *Made In China 2025* strategy, a ten-year national plan designed to transform China from a manufacturing giant into a global high-tech manufacturing power, will provide greater benefits to their operation in country over the next five years. Information gathered in the German Chamber of Commerce's *"Business Confidence Survey 2016"* show that these companies believe that this strategy will creat positive outcomes, despite an abundance of caution concerning evaluation in growth turnover and profit for the 2016 fiscal year. The survey interviewed 426 companies on issues related to business outlook, market conditions and investment climate.