

New Industry Partnership with Gavi to Strengthen Immunization Supply Chains in Developing Countries

IFPW recently announced a three-year, multi-million dollar partnership with Gavi, the Vaccine Alliance, to help address immunization supply chain needs in developing countries. This collaboration is the first of its kind for the global pharmaceutical wholesale industry as IFPW members make a commitment to strengthen supply chain management and ensure aspiring students in Gavi-supported countries receive the training needed to become the next generation of supply chain managers. Efforts will be primarily concentrated on supporting SCM training centers in Benin and Rwanda, which will serve multiple countries in Africa.

Specific support will flow through IFPW Foundation (IFPW's charitable and educational arm), in the form of both financial and in-kind donations from members and supporters, amounting to at least US\$1.5 million over three years. This contribution level qualifies the support for matching funds through the Gavi Matching Fund program, thereby doubling the impact of the investment.



IFPW Chair Ornella Barra with Bill Gates, Seth Berkley (CEO of Gavi) and others making private sector partnership announcements in Berlin.

Dr. Richard Sezibera, Secretary General for the East African Community, stated "This partnership brings forward the vision for the East African Community to become the regional center of excellence in health logistics.

We recognize the value of the private sector in helping achieve this vision and congratulate the IFPW and its members to working with us and Gavi, the Vaccine Alliance to achieve this."

Speaking on the eve of Gavi's Replenishment Summit in Berlin - which takes place days after the Vaccine Alliance celebrated its 15th anniversary - Ornella Barra, Chairman of IFPW commented: "I am thrilled to announce this fantastic partnership between the IFPW and Gavi, which, with the support and expertise of IFPW members, will help to address immunization supply chain needs in countries such as Benin and Rwanda. Millions of lives could be saved each year by improving access to existing medicines and vaccines. By investing in the long-term development of supply chains in Africa, I do believe the IFPW has a unique opportunity to make a difference."

"One of the largest obstacles to immunizing children in poor

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In Brief . . .

- ◆ **AmerisourceBergen** reported a 15.1% increase in revenue (to US\$33.6 billion) and gross profit of US\$896.3 million (+23.7%) for its fiscal 1st quarter ended December 31st. The revenue increase includes a 15% increase in AmerisourceBergen Drug Corporation revenue, due primarily to the onboarding of the new Walgreens generic pharmaceuticals business, strong sales of products that treat hepatitis C, and solid organic sales growth in ABC's independent pharmacy, health systems and alternate site customers. AmerisourceBergen Specialty Group revenues increased 26% in the quarter, driven by strong performance in blood products, vaccine and physician office distribution businesses, the impact of manufacturer shifts of certain oncology products from full line distribution to specialty distribution, strong performance in ABC's third-party logistics business, and an increase in sales to community oncology practices.

- ◆ The pharmaceutical industry in Japan is facing a wave of job cuts following worldwide reductions in healthcare spending and losses of patent protection for blockbuster drugs. Major Japanese drug makers that have recently cut their workforce include **Daichi Sankyo**, **Astellas Pharma**, and Eisai.

- ◆ Actavis will acquire Auden Mckenzie Holdings for approximately US\$465.8 million in cash, plus a two-year profit royalty on one of Auden Mckenzie's products. The acquisition will make Actavis the largest supplier of generic pharmaceuticals in the U.K.. Following the close of this acquisition and the anticipated combination of Actavis and Allergan later in 2015, Actavis will become 3rd largest supplier of pharmaceuticals in the U.K..

- ◆ US generic drug prices are increasing significantly in some cases, spurred by market opportunities, short-term market exclusivity for some newly-launched single-source generics and rising costs for manufacturing, quality control and raw materials. Given that generics comprise roughly 85% of all prescriptions dispensed in the United States, the impact is significant. "We're back to double-digit growth that we haven't seen in 10 years ... because of specialty drugs and price inflation," said Doug Long, VP industry relations for IMS Health. "There's a lot of generic price inflation; it's the No. 1 issue on the minds of many payers."

- ◆ **Mylan** will purchase the female healthcare segment of India's Famy Care for US\$750 million in cash and additional contingent payments of up to US\$50 million. The deal is expected to complement the firm's pending acquisition of Abbott's non-US specialty and branded generics business, and make Mylan a hormonal contraceptives leader in high-growth emerging markets around the world.

- ◆ According to a report from China Venture, there were 390 merger and acquisition deals in China's medical and healthcare sector in 2014, up 20% from the previous year. The value totaled US\$14.04 billion, up 70% from 2013, with the largest M&A case by value being Bayer AG's purchase of a 100 percent stake in Kunming Dihon Pharmaceutical for US\$586 million.

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GAVI (cont.) . . .

countries is getting the vaccines to them,” said Gavi CEO Dr. Seth Berkley. “Vaccines are temperature sensitive, and the infrastructure in poor countries often is lacking. Partnerships, such as this one with IFPW which represents engagement of a whole new industry, are bringing new thinking and resources to help the Vaccine Alliance reach every child.”

Other private sector partnerships were also announced by Gavi during its Berlin pledging conference for replenishment, including several with vaccine manufacturers (Biological E, GSK, Janssen, Merck, Panacea Biotech, Pfizer, Sanofi Pasteur and Serum Institute of India). A partnership was also announced with UPS, who will work with Gavi to leverage the expertise of its Global Healthcare Logistics Strategy Group to develop and implement an executive training and mentorship program to enhance the capability of local supply chain leaders. As such it was important for IFPW to be represented at this historic global health event to demonstrate the value pharmaceutical wholesalers provide and demonstrate the industry’s capabilities and sophistication within healthcare value chains.

The Ranking of Europe’s Healthcare Systems

(Sources: Health Consumer Powerhouse (based in Sweden) and an article prepared by Kevin Grogan and published by PharmaTimes)

Despite the financial crisis, healthcare in Europe continues to improve, with The Netherlands once again leading the Euro Health Consumer Index (EHCI) which ranks systems on 48 indicators covering six areas - patient rights and information, accessibility of treatment/waiting times, outcomes, range and reach of services, prevention and accessibility of pharmaceuticals. The Dutch system scored 898 points out of a potential 1,000, with the other top 10 countries being: Switzerland, Norway, Finland, Denmark, Belgium, Iceland, Luxembourg, Germany and Austria.

The sourced article emphasized that the following discussion does contain a substantial amount of speculation outside of what can actually be derived from the EHCI scores: The Netherlands (NL) is characterized by a multitude of health insurance providers acting in competition, and being separate from caregivers/hospitals. Also, the NL probably has the best and most structured arrangement for patient organization participation in healthcare decision and policymaking in Europe. Also, the Dutch healthcare system has addressed one of its few traditional weak spots – Accessibility – by setting up 160 primary care centers which have open surgeries 24 hours a day, 7 days a week. Given the small size of the country, this should put an open clinic within easy reach for anybody. As for speculation: one important net effect of the NL healthcare system structure would be that healthcare operative decisions are taken, to an unusually high degree, by medical professionals with patient co-participation. Financing agencies and external healthcare influences such as politicians and bureaucrats seem farther removed from operative healthcare decisions in the NL than in almost any other European country. This could be a major reason behind the NL landslide victory in the EHCI 2014.

As for real excellence in southern European healthcare, it seems to be a bit too dependent on the consumers' ability to afford private healthcare as a supplement to public healthcare.

German Generics Ban Delayed by Legal Challenges

(Source: An article prepared by Lynne Taylor and published by PharmaTimes)

Germany’s decision to withdraw 80 generic drugs from the market cannot apply to 18 of the products because of the legal challenges brought by their manufacturers against the ban, the national drug regulator has said.

On December 7, the Federal Institute for Drugs and Medical Devices (BfArM) said it was suspending, with immediate effect, the marketing authorizations (MA) of 80 products made by 16 companies, because of “serious and systematic deficiencies” in the bioequivalence studies conducted for the products by the Indian contract research organization (CRO) GVK Biosciences. However, BfArM has now said that the ban cannot be applied to 18 of the products until a decision is made on the appeals lodged by their manufacturers. It is reported that most of the 18 generics are produced by German drugmaker Betapharm, with Heumann Pharma and Stada also having launched appeals. The agency also said that those products whose sales have been suspended would be permitted to return to the market if their makers provide it with new clinical trial data.

In September, France’s Agency for the Safety of Health Products (ANSM) reported that it had found falsifications of electrocardiograms in nine studies carried out by GVK at its clinical development unit in Hyderabad, India, between 2008 and 2014. Then on September 24, the European Medicines Agency (EMA) announced that the Committee for Medicinal Products for Human Use (CHMP) would review studies conducted at the site and adopt a final opinion on whether the MAs of the products involved should be maintained, varied, suspended or withdrawn across the European Union (EU).

Since then, Belgium, France and Luxembourg as well as Germany have suspended the MAs for a number of generic drugs for which clinical trials were conducted at the site by GVK Biosciences. Commenting, GVK Biosciences says that in the last 10 years, its Hyderabad unit has been inspected more than 25 times by regulatory agencies, none of which have reported any critical findings. “We believe that the conclusions of the ANSM and the subsequent actions by the EMA are highly disproportionate to the actual risk posed to human health. At the same time, we respect and honor the conclusion made by the European regulators and are working with our clinical development customers to provide new data that meets all regulatory requirements,” said the company’s CEO, Manni Kantipudi.

The CHMP’s final opinion is expected this month. It will be forwarded to the European Commission, which will then adopt a legally binding decision.

In Brief (cont.) . . .

- ◆ Executives from one of Venezuela’s largest pharmacy chains, **Farmatodo**, are in custody for allegedly manufacturing shortages of basic necessities, hoarding and speculating in response to effects of collapsing oil revenue in the country. Venezuela has promised to increase state control of the distribution business in response.

(Sources: AmerisourceBergen, China Daily, Drug Store News, Pharma Japan, and Pharma Times)