FOCUS
Vol. 22 No. 25 International Federation of Pharmaceutical Wholesalers December 17, 2015

U.S. Trends that will Impact Health Care in 2016

(Sources: PricewaterhouseCoopers (PwC) and an article prepared by Jessica Merrill and published by Scrip)

Drug pricing – particularly the development of novel schemes to demonstrate value and support reimbursement of high cost specialty drugs – will be one of the key issues impacting health care in 2016, consulting firm PwC forecast in its annual Health Research Institute (HRI) report. The report, released Dec. 9, calls out 10 trends PwC expects will have enormous impact on health care in the year ahead. The biggest issues for the drug industry to keep an eye on are pricing, Merger & Acquisitions and biosimilars.

"Drug pricing is becoming an issue for all of the industry," Benjamin Isgur, director of thought leadership at PwC's Health Research Institute, said in an interview. "Frankly, it is starting to become more and more of a consumer issue, so I think that is the important thing for the pharmaceutical industry and the life sciences industry to understand." The issue has already become controversial in 2015, kindled by a handful of specific cases of exorbitant price hikes and further fueled by political rhetoric in the U.S. presidential election campaign. Leaders in the drug industry appear open to exploring new pricing and reimbursement models, including in some cases reimbursement linked to outcomes, but reaching consensus with payers on the issue has posed challenges. Thus far, there are very few examples of outcomes based pricing contracts in the US. No novel model has yet emerged out of the pricing debate, Isgur acknowledged. However, he predicted 2016 will be the year third-party organizations, ranging from government groups to nonprofit value assessment organizations, will take on a leadership role analyzing data, evaluating drug prices and assessing the value of new drugs coming to market.

One avenue that could be further explored is consumer financing of prescriptions, he said. In a survey conducted by PwC, 53% of respondents said they would be willing to pay the cost of a drug over time instead of at one time. This kind of payment system has already been adopted in other areas of health care, Isgur added. Biosimilars are one way payers are hoping to reduce specialty drug spending, which increased 27% in 2014, PwC said, citing IMS data. The consultants predicted that 2016 will be the year that biosimilars finally gain ground in the US, following the launch of the first biosimilar, Sandoz Inc.'s *Zarxio*, this year at a 15% discount to Amgen Inc.'s reference product *Neupogen*. But PwC warned that significant patient and physician education will be required. Most consumers have no idea what a biosimilar is, PwC said; 8 out of 10 consumers questioned in a 2015 HRI survey failed to choose the correct definition of a biologic from a short list of responses, the firm noted. "It's going to be a really big year for consumer education, and we think the pharmaceutical industry will have a big role to play in that," Isgur said.

At the same time, manufacturers of branded biologics will be working to defend their market positions against biosimilars.

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In Brief . . .

◆ **Celesio**, a business of McKesson Corp., is acquiring **Belmedis**, the 2nd largest wholesaler in Belgium (and the distribution business of French cooperative Welcoop) for an undisclosed sum. The transaction, subject to regulatory approval, also includes Cophana, a leading pre-wholesaler in Belgium and a majority stake in Sofiadis, a buying group of around 430 independent pharmacists.

◆ Finland's **Oriola-KD** has agreed to acquire Swedish pharmacy company **Svensk Dos** for an undisclosed sum. Svensk Dos specializes in dose dispensing of pharmaceuticals and services to people via extradition locations and nursing homes in the region of Skåne and direct to the Swedish Prison and Probation Service all over Sweden. In 2014, the company's net sales were approximately €25 million/US$27 million with an estimated market share of 13%. "The acquisition of Svensk Dos is an important addition into our new Healthcare business. Through this acquisition we can complement our growing service offering to the Healthcare sector", says Oriola President & CEO *Eero Hautaniemi*.

◆ **Valeant Pharmaceuticals** has signed a 20-year direct distribution agreement for its dermatology and ophthalmology products with **Walgreens** in a move to help reduce costs and administrative processes, yielding savings that can benefit patients and the healthcare system. As part of the agreement, which is also available to interested independent pharmacies, Valeant will reduce the wholesale price of its dermatology and ophthalmology products by 10% and will reduce the price of other products that have a generic equivalent – making its products available at the same cost as the generic alternatives. The price reductions are expected to range from 5% to 95%, with an average discount of 50%, and could be the basis of a new business model.

◆ Under the premise that of the most important yet simple ways communities can reduce prescription drug misuse is to encourage the proper disposal of unused/expired medications, **Cardinal Health Foundation** is accepting grant applications from US non-profit organizations operating or establishing programs to address the issue. The grant objectives are: increased awareness of the disposal programs and community members' participation in them; increased awareness of how to prevent prescription medication misuse, and the importance of proper disposal to that end; involvement of youth and pharmacists or student pharmacists in disposal programs; and measurement of the impact and outcomes of disposal programs.

◆ **Sanofi** and **Boehringer Ingelheim** are discussing an exchange of businesses which would involve Sanofi's animal health division, **Merial**, worth about US$12.4 billion and Boehringer Ingelheim's consumer healthcare business, valued at US$7.3 billion. If finalized, the deal (which would exclude BI's consumer healthcare business in China) would see Sanofi receiving a US$5.2 billion payment from Boehringer Ingelheim and make Sanofi one of the top over-the-counter product companies in the world.

(Sources: Cardinal Health, Celesio, Drug Store News, Oriola-KD, Scrip)

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U.S. Trends(cont.) . . .

Manufacturers aiming to defend their brands against competition should develop and promote complimentary services like mobile apps, patient education and financial assistance to build brand loyalty and discourage switching, PwC added.

Another trend that is already evident in 2015 and appears poised to continue rapidly in 2016 is M&A, PwC said. Largescale M&A and other deal making are likely to continue, while attention also will shift to the regulatory front, as some high profile deals await FTC approval. Several payers, including Aetna Inc. and Humana Inc., have announced large-scale mergers that are expected to close in 2016. Consolidation among insurers and pharmacy benefit managers puts more pressure on the pharmaceutical industry as the payers increase their leverage when it comes to negotiating drug contracts. A class of cholesterol drugs have offered a high profile example of payers attempting to address high cost specialty drugs, and new competition in hepatitis C could renew negotiation in that space. M&A activity has been prevalent in the pharmaceutical industry as well, which is similarly consolidating. The biggest news is Pfizer Inc.'s plans to merge with Allergan PLC in the largest merger in drug history, valued at roughly US$160 billion. The HRI report included seven other trends that are impacting health care in 2016, among them being cybersecurity associated with medical technology, particularly the threat to medical devices; increased cost management by consumers; the emergence of mental health as a priority health area; and, the development of new databases to manage big data.

Five Industry Trends for U.S. Pharmaceutical Wholesalers

(Sources: Modern Distribution Management; drugchannels.net; Adam J. Fein, Ph.D., founder and President of Pembroke Consulting, Inc. and CEO of the Drug Channels Institute)

1. *Growing U.S. Outpatient Pharmaceutical Spending Over the next 10 years:* spending on prescription drugs sold through outpatient retail, mail and specialty pharmacies is projected to grow by US$259.2 billion (+85%), to US$564.8 billion in 2024. Wholesalers will benefit from the expected overall growth in demand for prescription pharmaceuticals and the corresponding increase in drug spending.

2. *Consolidation and Changes in Pharmacy Industry Market Structure:* As the overall prescription market grows, Drug Channels Institute expects the pharmacy industry to continue consolidating and market share to become more concentrated. Consolidation and acquisitions, however, generally hurt wholesalers' margins, because the acquiring companies consolidate their buying power. Larger chains, which provide much lower profit margins for wholesalers, keep growing faster than other market segments. They are winning the battle for retail prescriptions with new store openings, organic growth from larger and busier pharmacies, and acquisitions of regional chains.

Significant recent transactions include: CVS Health's acquisition of Target's pharmacy business and intent to operate the pharmacies as a CVS branded, store-within-a-store format. Target had operated almost 1,700 stores with pharmacies. CVS Health also entered the long-term care and assisted living market by acquiring Omnicare. UnitedHealth's OptumRx acquired the pharmacy benefit manager Catamaran. Both companies operate large mail and specialty pharmacies. Independent drugstores, physician offices and other smaller customers are crucial customers for pharmaceutical wholesalers. Wholesalers provide a broad range of services intended to increase the profitability and competitive viability of their smaller, higher-margin customers.

3. *New Vertical Relationships with Large Retail Drugstores:* Over the past few years, wholesalers have successfully deepened their relationships with large retail chains. Large pharmacy retailers are shifting from self-warehousing to establishing direct-store deliveries from a wholesaler. Here are the two most significant changes: In 2013, AmerisourceBergen (ABC) took over distribution for the brand-name drugs that had been distributed from Walgreens' own warehouse network and by another wholesaler. Beginning in 2014, ABC assumed responsibility for generic products that Walgreens had historically self-distributed. In 2014, McKesson took over direct-store delivery of brand-name and generic drugs for Rite Aid, which no longer distributes drugs from its own warehouses. Wholesalers and retailers have also become more aligned in generic purchasing. Over the past three years, the big three U.S. wholesalers have established novel generic relationships with their largest customers: Walgreens Boots Alliance (with AmerisourceBergen); The Red Oak joint venture between Cardinal Health and CVS Health; McKesson's OneStop generic program, which is now utilized by Rite Aid.

In 2015, McKesson established McKesson Global Procurement & Sourcing Limited, a London-based subsidiary focused on manufacturer negotiations. The reduced acquisition costs from these retail-wholesale purchasing relationships are encouraging other pharmacies to shift generic purchasing to wholesalers. Examples include Albertsons, Fred's, Omnicare and OptumRx. These deals increase wholesalers' influence, by shifting generic volume to the wholesale channel. In addition, new vertical ownership relationships are also developing. Walgreens Boots Alliance can own up to 30% of AmerisourceBergen's equity and will have two board positions.

4. *The Promise and Peril of Specialty Drugs Revenues:* the pharmaceutical industry will shift from traditional brand-name drugs to specialty drugs over the next few years. To compete for the specialty drug opportunity, each wholesaler operates subsidiaries that focus on specialty drug distribution and related services. Payer strategies, however, create profitability risks for the pharmacy-dispensed specialty drugs that wholesalers sell. That's because these specialty product sales are being shifted into the largest specialty pharmacies (and wholesalers' largest customers) with the smallest margins for wholesalers.

5. *The Changing Generic Marketplace:* Generic drugs now dominate U.S. prescription activity. Wholesalers benefit from this trend, since a majority of their gross profits comes from generic drugs. Wholesalers have benefited from the unexpected and somewhat unprecedented increase in the prices of some generic drugs. However, Drug Channels Institute's analyses of pharmacy acquisition costs indicate that generic inflation was greatest in 2013 and 2014, and appears to have eased in 2015. Pressure on pharmacy profits from generic drugs is increasing, which will indirectly affect wholesalers that supply pharmacies. These challenges include a retail generic price war, the growth of narrow pharmacy networks, and new pharmacy reimbursement methods.