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Current Specialty Pharmaceutical Trends

(Sources: an article prepared by Kay Morgan, V.P. of Drug Products & Industry Standards and Clinical Solutions at Elsevier, posted by Drug Channels; Cardinal Health Specialty Solutions' 2017 Oncology Insights; McKesson; and, QuintilesIMS Institute)

Over the past decade, there has been a paradigm shift in the treatment of cancer, driven by advances in personalized medicine and immune-oncology. Drawing on advancements in biotechnology, specialty drugs work at the cellular level to offer the most effective, or sometimes only, treatment for complex and/or chronic conditions and illnesses that in the past had few options. With the ability to sometimes make the difference between life and death, they are highly prized — and priced. Consequently, health plans and industry stakeholders are developing strategies to manage rising specialty drug prices while ensuring access to these critically important drugs.

Competition to distribute these drugs remains strong, as established specialty pharmacies gain ground, community pharmacies find openings, payers establish adherence programs and control formularies, and retail and drug chains are staking claims in this potentially lucrative territory.

Specialty pharmaceuticals continue to grow both in number and percentage of drugs dispensed, a surge not expected to abate in the near future. Statistics show that about 30% of drugs sold in the United States today are specialty pharmaceuticals, with industry experts expecting that figure to reach 50% within the next three years. That prediction is based on nearly 700 new specialty drugs reportedly that were under development by the end of 2016.

Also on the upswing are specialty pharmacies. These organizations help to meet the challenges of storage and administration (i.e., injection or infusion) of these drugs; management of what can be more serious and frequent side effects; and aggressive outreach, monitoring and patient education to promote adherence.

As noted by McKesson, there are a variety of significant trends fueling growth and investment in the niche of specialty pharmacy. These trends include the escalating interest in "precision" medicine—which takes into account individual variability in genes, among other factors—and the sheer numbers of new patients in the care pipeline, some of whom may have more than one condition that requires a specialty drug.

McKesson also points to established FDA incentives to encourage drug manufacturers to find treatments for rare genetic diseases. This "Fast-Track" designation recently gained even more strength with passage of the 21st Century Cures Act, which not only eased regulatory processes for affected drugs and medical devices, but also earmarked billions of dollars in new funding for research into areas such as cancer and Alzheimer's disease.

The dilemma of effectively delivering these drugs to needy patients is that manufacturers are spending vast amounts of money on R&D and justify costs by that investment. Patients can't take medicine they can't afford to buy, causing them to reduce, stop or never start taking what could be life-saving therapy. And everyone in between has to maintain viability and wants equity.

Avenues being explored for controlling costs include: (a) changes in adjudication coding to provide the level of detail necessary for a clear picture of what is being used and how; (b) resolution of the definition of a "specialty drug" during payer/pharmacy benefit manager contracting and negotiation to assure clarity and transparency into drug pricing and rebates; (c) utilization management, such as step therapy, in which less expensive, alternative therapies are tried first; prior authorization; quantity limits; and partial fills; and, (d) building on advances in adherence programs to ensure the value of therapy is being optimized at the lowest possible cost.

Other cost solutions include the entry of biosimilars into the market. Biosimilar drugs are highly similar to branded drugs and

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In Brief...

- The **International Federation of Pharmaceutical Manufacturers and Associations** (IFPMA) announced the launch of the **Anti-Microbial Alliance** at the B20 meeting in Berlin. This falls in line with the *Industry Declaration on AMR at the World Economic Forum* in Davos in 2016. The goal of the Alliance (which includes pharmaceutical, generics, diagnostics and biotech companies) is to reduce the development of anti-microbial resistance, promote access to effective antibiotics, vaccines and diagnostics, and invest in research and development.
- **UPS** announced the opening of a new healthcare logistics facility in Colombia. The goal of the new facility is to assist pharmaceutical, biopharma and medical device companies in creating a seamless supply chain in Latin America. UPS will offer distribution services, warehouse management and late-stage customization solutions for labeling, product kits and repackaging. The facility was opened on June 5, 2017.
- Efforts to pay down debt have lead **Valeant Pharmaceuticals** to sell its **iNova** unit for US$930 million to **Pacific Equity Partners** and the **Carlyle Group**. iNova operates in 15 countries and specializes in prescription and over-the-counter products for a variety of health-related solutions.
- Newly-elected **WHO** director-general, *Tedros Adhanom Chebreyesus*, has challenged governments to set meaningful goals to achieve universal healthcare coverage. During his remarks, Tedros stated that "if there is no health, there is nothing" and that "health for all should be front and center of all development efforts." He also added that the WHO is "ready to articulate this very well and help countries to achieve the universal health coverage that we have promised for 70 years now." Universal health coverage is specifically referred to in the UN's Target 3.8 in the *Sustainable Development Goals*.

(Sources: Intellectual Property Watch, PharmTech.com, Press Releases, and TheStreet.com)

Current Specialty (cont.)...

could do for specialty drug pricing what generic drugs did relative to brands, that is, significantly lower costs.

Specialty drugs have their own unique set of challenges. While addressing the expense of specialty pharmaceuticals, stakeholders must also focus on ways to manage costs along with programs that impact the health and quality of life of the patient in treating the complex nature of the disease with complicated drug regimens.

Cardinal Health Specialty Solutions recently introduced *2017 Oncology Insights*, the first in a series of research reports to provide perspective on key issues for specialty care providers, biopharma companies and other healthcare stakeholders. The report documents how oncologists view critical issues impacting their practices, including the transition to value-based reimbursement, use of real-world evidence to make treatment decisions and the role of pharmaceutical companies in providing patient support services.

"Oncology care has never been more complex, with a variety of issues creating both challenges and opportunities for those working to advance cancer care," said Joe DePinto, president of Cardinal Health Specialty Solutions

In a report by QuintilesIMS Institute, cancer continues to be one of the leading causes of morbidity and mortality worldwide. Therapeutic innovation based on improved understanding of the disease biology and the translational research have considerably changed the treatment paradigm for many cancers. From 2011 to 2016, 68 new drugs have been approved for 22 indications. Currently there is a robust pipeline of over 600 molecules in late stage development of which 90% are for a targeted therapy . At the same time, newer treatment options, including biomarker-based treatment approaches, have added to treatment complexity. Novel oncology treatments are reaching physicians faster than ever, but the availability of newly launched agents differs substantially by geography.

Global costs of oncology therapeutics and supportive care drugs increased from US$91 billion in 2012 to US$113 billion in 2016 (a growth rate of 11.6%), with the United States accounting for 46% of the total global oncology costs. Longer duration of therapy with novel agents, use of combination therapies with high cost novel agents and the possibility of patients receiving multiple lines of therapies are factors likely to contribute to further increases in costs. Uptake of newer agents and increasing use of older branded drugs are the contributing factors for cost increases in other regions of the world. The cost of supportive care treatments increased at a compound annual growth rate of 2.0% in 2016.

4 Major Japanese Wholesalers Impacted on Hep C Pullback &Price Revision

(Source: Pharma Japan)

Four leading Japanese drug wholesalers all suffered lower revenues and profits in their pharmaceutical wholesaling businesses in FY2016, which ended on 31 March, with a pullback in demand for Gilead Sciences' hepatitis C drugs, significantly affecting their primary distributors, Suzuken and Toho Holdings, a Jiho tally showed.

In the year ended March 2017, Suzuken derived sales of 90.2 billion yen (US$823 million) from hepatitis C therapies, of which 85.2 billion yen (US$77.8 million) came from Gilead products. This is nearly half the of the 170.9 billion yen (US$1.56 billion) it gained in revenue from hepatitis C medications in the previous year, which included 157 billion yen (US$1.4 billion) from Gilead products. The decline sent Suzuken falling back to third place in the drug wholesaling business ranking, just a year after it rose to second position in FY2015.

Toho Holdings, meanwhile, saw sales of Gilead products decline from 105 billion yen(US$958 million) in FY2015 to 60 billion yen (US$547.7 million) in FY2016. For FY2017, Suzuken and Toho Holdings both expect Gilead hepatitis C sales to shrink further to 30 billion yen (US$274 million) and 15 billion yen (US$137 million), respectively.

The four major wholesalers which also include Alfresa Holdings and Medipal Holdings all posted declines in wholesaling revenues in FY2016. Even excluding the impact of Gilead products, Suzuken and Toho Holdings also recorded falls in revenues. The results came as generic erosions lowered sales of larger margin long-listed products (LLPs), or off-patent original drugs. Further, a biennial drug price revision was carried out in April 2016, with new special repricing for “huge seller” drugs.

In FY2016 (ended March 2016), the average operating profit rate for the four wholesalers came to 1.18% on a consolidated basis, including non-wholesaling operations. This was up 0.17 point versus FY2014 (ended March 2014), when the previous drug price revision was implemented, apparently due to the companies' efforts to counter headwinds such as generic inroads and proposed annual drug price revisions.

Medipal Holdings, which is working to diversify its revenue streams, was the only one of the four to deliver higher consolidated revenues year on year, albeit lower profits, with the other three organizations seeing lower profits on lower sales. At an earnings conference, Medipal Holdings President Shuichi Watanabe highlighted that diversification holds the key to growth. The company is focusing on new drug promotions by wholesaler representatives, who have “medical representative” certificates. In FY2018, it plans to spend 11.8 billion yen (US$107.7 million) for the construction of a logistics center that would help it expand its consumer healthcare business.

Alfresa Holdings is also moving to expand its contract API manufacturing business, and introduce robots at its ethical drug logistics center. It also intends to boost productivity by optimizing logistics sites in a bid to keep abreast of the ongoing transformation of healthcare delivery systems into community-based systems.

Suzuken is set to launch reforms to reduce the selling, general and administrative (SGA) cost ratio by 1% over three years through FY2019 (ending March 2019) such as reducing overtime work. According to a Jiho tally, the company has had the highest SGA ratio among the four majors for 12 straight years through FY2016 (ended March 2016). Elsewhere, the wholesaler is looking to bring out added value by launching new IT-based distribution services for high-priced specialty medicines by partnering with US companies. Toho Holdings made its foray into the generic sales and manufacturing business by starting Kyosomirai Pharma in November last year, with two APIs/three products rolled out in the following month. The company is also looking to enhance its profitability by broadening its non-wholesaling business centering on sales of IT systems to support customers, such as pharmacies.