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Cardinal Health Acquires J&J's Cordis

(Sources: Cardinal Health and an article prepared by Selina McKee and published by PharmaTimes)

Johnson & Johnson is selling its vascular medical technology group Cordis to US pharmaceutical service provider and distributor, Cardinal Health, for US$1.94 billion, severing its ties with the field. Cordis had annual sales last year of around US$780 million, split between cardiology and endovascular products. Cardinal says it expects the acquisition to add more than $0.20 in earnings per share from fiscal 2017.

The move will significantly boost interventional cardiology and endovascular products, such as heart stents and catheters, Cardinal can offer hospitals and physicians, in line with a broader strategy of increasing its portfolio of medical device products.

Headquartered in Fremont, Calif., Cordis' annual sales in 2014 was split almost evenly between cardiology and endovascular products. Cordis is a global company with a growing portfolio of products serving healthcare systems throughout the world. While the U.S. is the largest single market, 70% of total sales come from outside the U.S. Cordis' international presence includes operations in more than 50 countries, including China, Japan, Germany, Italy, France, the United Kingdom, and Brazil.

"With an ageing population and the accompanying demand for less invasive medical treatments, health systems around the world are searching for the best way to bring quality care to their patients in the most cost-effective way. The acquisition of Cordis reinforces our strategic position to address this need and strengthens an important growth driver in the Cardinal Health portfolio," said chief executive George Barrett, further explaining the decision.

The deal, which Cardinal expects to fund with a combination of US$1.0 billion in new senior unsecured notes and the remainder with existing cash, is expected to close in the US and key non-US countries towards the end of this year.

In Brief . . .

- Spanish wholesaler and retailer **Cofares Group** ended 2014 with a national market share of 24.54% and a consolidated turnover of €2.65 billion / US$2.9 billion. The Ebitda generated, less impairment losses, reached €45.7 million / US$50.6 million, and Cash Flow reached €67.6 million / US$74.9 million for the year.
- **Cardinal Health** named *Nick Calla* as VP industry relations, Cardinal Health Specialty Solutions. Calla's role will focus on the creation of specialty pharmacy programs that connect manufacturers with retail independent pharmacies — and includes the development of the *Specialty Pharmacy Alliance*, a specialty resource center.
- Gross margins for pharmaceutical wholesalers in Germany fell to 4.67% in 2014, according to Germany's national wholesalers' association, **PHAGRO**.
- **Johnson & Johnson** has formed a new health-and-wellness platform, *Johnson & Johnson Health and Wellness Solutions*, which will facilitate the development and implementation of programs that center on wellness and prevention, behavioral health and chronic disease support; all focusing on improving the quality and vitality of life.
- *Olivier Brandicourt* has been confirmed as the new CEO of **Sanofi**, coming from **Bayer** and succeeding *Chris Viehbacher* - who left the company in October.
- **Takeda Pharmaceutical** COO *Christophe Weber* will assume the role of CEO in April. Weber succeeds *Yasuchika Hasegawa*, who will remain as chairman, and the COO post will be eliminated.
- **GlaxoSmithKline** is selling its opiates business in Australia to Indian drugs giant **Sun Pharmaceutica**l for an undisclosed amount. Separately, GSK announced that *Sir Christopher Gent* will step down as Chairman of the Company on May 7th at its Annual Meeting. Gent will be succeeded by *Sir Philip Hampton*.
- While **Mylan Inc.** has completed the acquisition of part of **Abbott Laboratories'** specialty and branded generic business, the Japanese arms of the two companies will continue to operate separately for the time being. Mylan announced on February 27th that it had bought Abbott's specialty and branded generics business in non-US major markets, including Japan.
- **Actavis**, upon a successful completion of the acquisition of **Allergan** will use the Allergan name as its corporate name and for its global branded pharmaceutical portfolio. It will retain the Actavis name for select geographic regions and product portfolios.
- According to Japan's Ministry of Health, Labor and Welfare (MHLW), the market share of generics in Japan (by volume) rose 8.5 points from a year earlier to reach 55.0% through September 2014. **IBM** is expanding the *IBM MobileFirst for iOS* portfolio of apps for retailers **Boots U.K.** and **American Eagle Outfitters** are among the retailers who have signed on for MobileFirst apps. "The pilot of the IBM MobileFirst for iOS Sales Assist app will seek to explore how we can further empower our colleagues to be able to turn each customer interaction into a unique and personal experience," said *Robin Phillips*, director of multichannel, Boots U.K. "Boots colleagues will have access to real-time data and insight from across the company in the palm of their hands, allowing them to offer shoppers even greater levels of service-including real-time stock availability and easy in store ordering."

(Sources: Cofares, Drug Store News, GlaxoSmithKline, PHAGRO, Pharma Japan and Pharma Times)

Three Emerging Issues in Life Sciences' Supply Chain re Serialization

(Source: an article prepared by Dan Walles - VP, Solution Architecture and Global Partnerships, TraceLink – and published by SupplyChainBrain)

(Editor's note: Mr. Walles' article addresses a holistic, global view. In reality this may not be practical or appropriate. However, the issues cited in his article are certainly valid on a market-to-market basis)

With the lot-level traceability now implemented in the U.S. as of Jan. 1 under the U.S. Drug Supply Chain Security Act (DSCSA), many pharmaceutical companies are turning their attention to full drug serialization. DSCSA requires that manufacturers mark packages with a product identifier, serial number, lot number, and expiration date by 2017. In that period, highly regulated packaging and distribution processes must be changed; physical equipment must be procured and operationalized; enterprise-wide IT must be implemented; and end-to-end serialization testing with supply chain partners must take place well in advance of the deadline in order to allow time for necessary adjustments. Given these multi-faceted complexities, three years is an aggressive implementation time frame. Within the next three to five years, the vast majority of product volumes will be serialized. According to the article there are three current issues that will impact decision-making processes for pharmaceutical companies and their solution strategies.

*I***ssue #1: The scale and scope of producing products and moving them through the supply chain network will become increasingly complex and, therefore, a better understanding of the flow of products through the global supply chain will be required.** Presently many companies are 40% to 50% virtual. The focus will be on packaging, integrating a diverse network of processes and participants.

During the lot-level traceability implementation, some manufacturers realized that due to wholesaler operations, their requirements under the law were different than they initially assumed. Accordingly commercial agreements with partners, how might they change over time, and their impact with compliance will require a review process. When serialization takes effect, the ability to connect with partners and track all different operational requirements will be more critical than ever. Selecting a data management architecture that will collaborate with all external parties will be critical given their different technical capabilities, data formatting choices, roles within the supply chain, and relationships. Selecting a platform that allows seamlessly exchange of serialization data and streamline communications will be essential

Issue #2: Data and transaction volumes are growing exponentially. Serialization will introduce a massive new volume of data, and with that comes storage and processing challenges. Most companies have not calculated the exact volumes they'll be managing, which is an important step. The calculation is complex, however, considering the number of products and volume that is generated; the total number of serial numbers that will be need for ongoing basis; and the number of events against those serial numbers that will have to be track and stored. The process of tracking will need to be at scale, in real time, in conjunction with all other operational processes. For many companies, the end result is billions of records – and terabytes of data – that will need to be retained and available in a retrievable state for up to twelve years.

Consider a pharmaceutical manufacturer that packages 125 million items annually. For each item, a range of serial number management events – generated, reserved, commissioned, decommissioned, and destroyed – need to be tracked. In addition, other operational events must be tracked, such as packed/repacked, picked, shipped, received, quality released, recalled, damaged, and expired. If this manufacturer packs 24 items per case and 120 cases per pallet, for a total of 5,208,333 cases and 43,403 pallets, the yield of serial numbers commissioned annually is 130,251,736, all of which must be individually addressable and available for audit purposes.

From there, each serial number will have approximately 5 events a year for an annual event total of 651,258,681 events. The manufacturer will need to keep the records for twelve years – seven years past the average expiry of five years. In a steady state, that equates to 1,563,020,833 serial numbers and 7,815,104,167 events. With each event at 1KB per number, the annual serialization repository growth is 651 gigabytes a year, with a steady state serialization repository of 7.815 terabytes.

Data storage is much more affordable than it used to be, so cost isn't the primary issue. Rather, companies will need to look at the scalability of storage associated with their serialization solution.

Issue #3: The global footprint of the pharmaceutical industry continues to expand. Almost all companies in today's supply chain operate globally, so U.S. Drug Supply Chain Security Act (DSCSA) requirements are not the only ones they will need to be addressed in the next three to five years. The European Union, China, Brazil and South Korea are just a handful of countries implementing new regulations. To add to the complexity, no two countries have the same requirements, whether it is for the serial number that is place on the primary and secondary packaging, or the information needed to exchange with supply chain partners or submit to a regulatory agency. Products shipped to China, Brazil and Europe, for instance, require three different primary serial number formats: a government-issued 20-digit EDMC code for China; a non-GS1, manufacturer-issued 13-digit code for Brazil; and a GS1-compliant GTIN manufacturer issued code for the European Union. All three of these situations have different requirements on how information is exchanged to include China's manual file upload and download system; to Brazil's XML integration between the manufacturer, ANVISA, and throughout the entire supply chain; to Europe's integrated data exchange between stakeholders and the hub and national systems. Further there are different requirements for Turkey, Argentina, South Korea and more. Consequently the platform and architecture selected for serialization will need to meet diverse market requirements. Serialization will bring a greater level of security to the life sciences supply chain, a benefit that is ultimately passed on to patients. For pharmaceutical companies, though, the unavoidable truth is that it will impact many aspects of operations.