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Update: U.S. Track and Trace System

(Sources: Edited excerpts from a "blog" prepared by Michael N. Druckman and James S. Allred and the U.S. Federal Register dated July 20, 2017)

The U.S. FDA published two announcements in the Federal Register related to the development of an electronic, interoperable system to identify and trace certain prescription drugs distributed within the United States, pursuant to Congressional mandates in the Drug Supply Chain Security Act (DSCSA). The notices announce a new pilot program to evaluate electronic tracking methods and a series of meetings for FDA to solicit stakeholder input on developing such a system.

Passed in November 2013, DSCSA introduces a variety of requirements for manufacturers, wholesale distributors, repackagers, dispensers, and third-party logistics providers to track and trace certain prescription drugs as they move through the supply chain and to verify the identity and history of product as it is distributed. One of its provisions requires that a system for the "interoperable, electronic tracing of product at the package level" go into effect by November 27, 2023. Once operational, the system must permit the exchange of transaction information and transaction history between manufacturers. wholesale distributors, third-party logistics providers, repackagers, and dispensers "in a secure, interoperable, electronic manner."

As part of the process of developing this system, FDA is directed to conduct at least 5 public meetings to gather ideas on strengthening the safety and security of the supply chain and to oversee at least one pilot program "to explore and evaluate methods to enhance the safety and security of the pharmaceutical distribution supply chain." In these notices, FDA announces the commencement of both efforts.

For the pilot projects, FDA is recruiting participants from the pharmaceutical distribution supply chain and other stakeholders. FDA asks participants to propose the design and execution of their own pilot project, but will share "learnings" among all members. FDA encourages participants to focus their proposed projects on the interoperable, electronic tracing of product at the package level. FDA has identified a long list of issues to examine in the areas of Product Identifier, Barcode Quality, Interoperability, Data/Database/System Issues, Aggregation/Disaggregation, Verification/Notification, Exception Handling of Errors/lnconsistencies, and Special Scenarios.

To apply, interested stakeholders should submit a request with contact information, names of all partnering entities that would participate, the types of partnering entities participating, the number of employees for each partnering entity that would participate, proposed start and finish dates, a commitment to begin the project within 4 months of acceptance by FDA, a list of products to be used in the project, a list of locations where the project will be performed, and a description of the pilot project, including its goals, objectives, processes to be studied, and evaluation methods. Pilot projects should not exceed 6 months in duration. Participants

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- This week **Cardinal Health** put its China unit, **Cardinal Health China**, up for sale garnering interest from **Shanghai Pharmaceutical Holding Co., Ltd, China Resources Pharmaceutical Group Ltd.** and **Sinopharm Group Co., Ltd.** Sources close to the matter state that the deal may be worth up to US$1.5 billion. Cardinal Health China is one of China's largest drug distributors, and operates 16 distribution centers in 20 cities. In 2015, it generated more than US$3 billion in revenue.
- **Walgreens Boots Alliance** (WBA) has announced that it has a binding offer from **Fareva** to take over WBA's contract manufacturing unit, **BCM** in a 10-year global agreement. Under the terms of the agreement, Fareva will take ownership of BCM's business, which operates manufacturing facilities in the U.K., France and Germany. BCM manufactures beauty brands and private label products, including products sold in the U.S. The agreement also provides WBA with a core multinational manufacturing and development resources which will assist in the acceleration of the company's global market strategy.
- According to **Crecon Research and Consulting**, Japan's ethical drug sales ticked up 1.7% in May, as compared with the

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Home Healthcare Products Increase Demand in Pharma Logistics Market

(Source: Jim Butschli, editor of Healthcare Packaging)

The rising demand for the home healthcare products is the major driver for the pharmaceutical logistics market, which is experiencing continuous growth in order to meet the increasing demands of the pharmaceutical industry.

According to Grand View Research's (GVR) report assessing the pharmaceutical logistics market from 2015-2022, maintaining integrity, improving the costs of the supply chain and reducing distribution costs by forming a single-source distribution channel are boosting the pharmaceutical logistics market. GVR says the increasing importance of fast-track assistance and simple communication has also increased the demand for pharmaceutical logistics, as has merger-and-acquisitions between private-sector companies along with economic reforms.

The report segments the pharmaceutical logistics market on the basis of types of logistics and procedures, including sea and air freight, overland and integrated logistics. Procedures within pharmaceutical logistics include picking, storage, retrieval systems and handling systems. GVR segments regional pharmaceutical logistics markets in North America, Europe, Asia Pacific, Latin America and MEA.

The report cites the World Health Organization's estimation that the global market for pharmaceutical logistics is estimated to be approximately US$300 billion per year and is projected to grow to US$400 billion in the coming three years. The Asia Pacific region, says GVR, is expected to grow thanks in large part to emerging economies such as India and China.

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are expected to submit status reports during the project and a final report within 30 days of completion.

For the public meetings, FDA has announced a schedule of three public meetings to discuss topics related to the safety and security of the pharmaceutical supply chain. The proposed meetings are as follows:

• August 23, 2017: A discussion "What supply chain security should look like in 2023" and "What is needed for enhanced drug distribution security." Advanced registration closes July 31, 2017. A comment period on these topics will remain open until September 22, 2017.

• December 5-6, 2017: A discussion on "What is needed for electronic interoperability," "Standards for product tracing," "Data architecture options for an electronic interoperable system," and "The management and maintenance of product tracing data." Advanced registration closes October 27, 2017. A comment period on these topics will remain open until January 5, 2018.

• February 28, 2018: A discussion on "The use of aggregation and interference for enhanced product tracing and verification" and "Building capacity for a unit-level system for product tracing and verification." Advanced registration closes January 26, 2018. A comment period on these topics will remain open until March 30, 2018.

All meetings will be held on FDA's White Oak campus in Maryland and will be simultaneously webcast. The authors noted that the pilot program and meetings provide an opportunity for interested stakeholders to offer feedback and raise concerns with the agency about the design and implementation of the electronic information exchange system. The authors further stated that this gives stakeholders the opportunity to submit comments during the FDA process of developing an idea of how to configure a tracking system. Nevertheless, participation in the pilot program, as announced by FDA, consists of many demands, and thus it is unclear what benefit might be realized by participants.

China to Slash the Number of Drug Distribution Groups

(Source: an article prepared by Tom Hancock in Shanghai, with additional reporting by Xia Keyu, and published by the Financial Times)

A state initiative to reduce intermediaries in China's pharmaceutical market is expected to more than halve the number of companies in the sector, but experts say the government will struggle to achieve its aim of cutting drug prices and tackling bribery in distribution chains.

The clear majority of China's US$110 billion in annual pharmaceutical sales are to state-run hospitals, which depend on drug and medical equipment sales for most of their revenue. Drug sales are conducted through a complex network of some 13,500 distributors, with kickbacks to doctors being widespread.

Regulations limiting the number of invoices between drugmakers and hospitals to a maximum of two will be rolled out nationwide by next year, the State Council said last month. The number of drug distributors is expected to plummet as a result. "Reducing the number from more than 10,000 to 2,000-3,000, that is what I have heard from officials," said Xie Qilin, deputy secretary-general of the Chinese Medical Doctor Association. The "two invoice reform" as it is known is already being tested in 11 provinces, with Fujian in the east reporting a halving of distributors since its adoption in 2012. "The market is not concentrated enough," Wu Zhen, vice-minister of China's food and drug administration, said last year, explaining the rationale for the policy.

"The agencies will have to enlarge or die," said an employee at an overseas medical device manufacturer. The sector employs more than 3 million people, many of whom will be forced to switch to larger companies or change professions, the Economic Observer newspaper reported.

Eric Carlson, a partner at law firm Covington & Burling, said in a recent report that the crackdown on small distributors would accelerate sector consolidation, "centralizing distribution in a handful of pharmaceutical distributors, many of which are state-owned or state-controlled". Beneficiaries would include companies such as Sinopharm Group, in which the Chinese government has a majority stake, with Fosun Pharma as a partner.

The reform is likely to be more of a challenge for Chinese drugmakers that typically distribute their products indirectly, through local intermediaries. If applied to the medical device market it could benefit overseas companies by reducing the need for complicated supply chains. Ireland-based Medtronic, for instance, was fined US$17 million by Chinese anti-monopoly authorities last year for price fixing in its multi-layered local distribution system.

Other large multinationals tend to have their own sales teams, which employed some 20,000 staff as of 2011, according to Rachel Lee, an industry observer. But use of direct sales staff has not prevented bribery. GlaxoSmithKline paid a record £297 million (US$387.3 million) fine in 2014 after its sales staff were found guilty of corruption, while Bristol-Myers Squibb faced US$14 million in US penalties over alleged bribery of Chinese hospital officials. Novartis agreed to pay US$25 million last year over similar charges.

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previous year. Growth in cancer drugs were held down due to the impact of the lingering effects of a 50% price cut in *Opdivo*. Crecon's report is based on sales of pharmaceutical wholesalers to healthcare providers. Separately, it was reported that the generic use rate in Japan in FY2016 through March was at 65.5% based on volume. This is a 59.5% increase year over year according to the **Japan Generic Medicines Association** (JGA).

◆ China's **Ministry of Human Resources and Social Security** that the prices of 36 drugs will be cut and added to the list of pharmaceuticals covered by China's medical insurance fund. These drugs all shared the commonality of being so expensive that ordinary patients could not afford them and they were deemed medically necessary for certain illnesses, with no substitute available.

◆ In its first US launch under a global biosimilar partnership with **Samsung Bioepis**, **Merck** introduced its *Renflexis* (*infliximab-abda*), a biosimilar of *Remicade*. The company said that *Renflexis* would be launched with a wholesaler acquisition cost of $753.39, which represents a 35% discount to *Remicade's* current list price. *Remicade* was the 5th best-selling drug in the United States in 2016 with US$5.3 billion generated on an invoice price basis, according to QuintilesIMS data.

(Sources: Business Wire, China Daily, Drug Store News, Pharma Japan & Reuters)