

European Medicines Verification System (EMVS) Goes Live Across the EU

(Source: *European Medicines Verification Organization Press Release*)

On February 8th, the European Medicines Verification Organisation (EMVO) announced that its European Medicines Verification System (EMVS) went live across Europe in an effort to strengthen the safety and efficacy of the supply chain for dispensing drugs to patients. Going forward, all prescription medicines dispensed in Europe will be verified for authenticity by the EMVS. The establishment of the EMVS represents an unprecedented step towards preventing falsified medicines from entering the legal supply chain.

By implementing the EMVS, stakeholders in the pharma industry have put patient health and safety at the forefront. It is estimated by the European Commission in its impact assessment, which accompanied the Falsified Medicines Directive, that the prevalence of falsified/counterfeit medicines in the European legal supply chain is approximately 0.005%.

The EMVO was established in 2015 in accordance with the FMD (Directive 2011/62/EU) and the associated Delegated Regulation (EU/2016/161). Members of the EMVO organizations include pharmaceutical manufacturers, parallel importers (Medicines for Europe, EFPIA, EAEP), wholesalers (GIRP), community pharmacists (PGEU), and hospitals and hospital pharmacies (EAHP, HOPE). Technical developments of the EMVS were solely funded by pharmaceutical manufacturers and parallel importers. Wholesalers and pharmacies contribute to the governance of EMVO and the national systems, meaning that the public makes no financial contribution to the program.

“The EMVS has a unique structure that really makes it one of a kind. It will connect around 2,000 pharmaceutical companies, around 6,000 wholesale distribution authorization holders, 140,000 pharmacies, 5,000 hospital pharmacies and around 2,000 dispensing doctors in 28 EEA countries,” stated Hugh Pullen, President of the EMVO. He added “It would not have been possible to reach this landmark without a strong EMVO team and the substantial coordination between all stakeholders in the pharmaceutical supply chain. EMVO will ensure that the system remains technically stable, secure and that any issues are ironed out without any disruption for patients or the pharmaceutical supply chain. Looking beyond Europe, the system set up by the EMVO could well serve as a blueprint for securing the supply of medicines outside of Europe.”

The system works in three ways. First, pharmaceutical manufacturers and parallel importers will now serialize the packaging of their prescription medications with a unique identifier which will be imbedded in a two-dimensional matrix. They will also seal the packaging with tamper-resistant verification feature. These unique identifiers are then uploaded by the manufacturer to the European Hub (the EMVS).

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- ◆ **IQVIA's** financial results for Q4 and FY 2018 were announced with revenues of US\$2.4 billion, an increase of 8.1% year-over-year. Revenue FY 2018 was US\$10.4 billion, an increase of 6.8% over 2017 and net new business growth for 2018 reach 28.9 percent. Clinical research reached US\$1.4 billion for Q4, and IQVIA's technology and analytics solutions showed impressive results of US\$1.2 billion. Management suggested that TAS momentum would likely continue in 2019 with 100 pending contract wins for its orchestrated customer management (OCE) platform, which connects sales, marketing, medical and other functions.

- ◆ **Merck & Co. Inc.** announced a deal to buy **Immune Design Corporation** for US\$300 million. Immune Design's proprietary *GLAAS* and *ZVex* technologies help activate “the immune system's natural ability to generate and/or expand antigen-specific cytotoxic immune cells to fight cancer and other chronic diseases. The deal is likely to expand Merck's oncology franchise, which has been performing well thanks to its cancer drug *Keytruda*.

- ◆ Louisiana's largest non-profit academic health system, **Oschner Health System**, has entered into a multi-year strategic alliance with **Pfizer, Inc.** to develop innovative models for clinical trials. Through this partnership, Pfizer and Oschner (through its innovation lab, InnovationOschner along with Oschner Research) will explore ways to enhance the clinical trial experience and ease participation for both patients and healthcare professionals.

- ◆ The **Ministry of Health, Labor and Welfare (MLHW)** of Japan is moving to amend the *Pharmaceuticals and Medical Devices Law* with a related bill expected to be submitted in

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McKesson's Staying Power Comes From Adaptation

(Source: *An article by David Salazar, and an article by Sandra Levy, both for Drug Store News*)

McKesson Corporation, now approaching nearly 200 years old, is no stranger to change, particularly this year as the company moves its headquarters from San Francisco to Las Colinas, Texas. It will also experience a leadership change as current president and COO, Brian Tyler, takes on his new role as CEO.

Through all the changes, McKesson remains keenly focused on its customers and how to best serve them through its pharmacies which include national chains such as Walmart, regional chains such as Lewis Drug, and independent players who operate under McKesson's Health Mart banner.

“When we think about the future of retail pharmacy, we think independent and community pharmacies play a critical role in the health of the communities they serve,” Tyler said. “Supporting

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Once uploaded, wholesalers and other stakeholders in the supply chain will scan the data matrix on the outer packaging using specifically-designed software. The scan will verify the authenticity of the medicine as it travels through the supply chain. The verification of the unique identifier happens through the National Medicines Verification System (NVMS). Individual national systems will be connected through the European Hub to make them interoperable. Medicine manufacturers will also upload the data of the medicinal products through a secure connection through the European Hub.

Lastly, the dispensing pharmacist, hospital pharmacist, or (in some cases) the wholesaler will decommission the unique identifier before dispensing products to the patient. This ensures the final safety measure for the endpoint verification of the medicines' authenticity.

For more information on the EMVS, please visit http://girp.eu/sites/default/files/documents/the_european_medicines_verification_system_explained_v1.0.pdf. (There will also be a panel discussion at the IFPW 2019 CEO Roundtable, May 9th-10th at the Corinthia Hotel in London.)

McKesson (cont.)...

these pharmacies and finding new ways to help them improve the care they deliver – all while reducing costs and improving efficiency – are a key focus for us. Community pharmacies are an important part of addressing healthcare's overall challenges.”

Indeed, these independent pharmacies underscore Health Mart's partnership, resources and driving factors in their success as they go up against pharmacy giants such as CVS Health, Walgreens Boots Alliance and others in a rapidly-evolving environment. But through it all, independent pharmacists emphasize it is a great time to be a pharmacy owner.

With its strong value proposition, McKesson executives say that the company is shaping the future of retail pharmacy by emboldening its Health Mart pharmacies to set themselves apart so they can grow in a more complex landscape with the goal of ensuring their success over the long term. One of the key tools in this is the MyHealthMart dashboard, which enables independents to run their business more efficiently and cost-effectively.

McKesson also enables its customers to enhance their offerings by leveraging its distribution network, through which roughly one-third of the nation's medications pass on a nightly basis, according to Gene Cavacini, Senior Vice President and COO of U.S. Pharma.

“If we're doing our pick, pack and ship job right, no one ever thinks about us,” Cavacini said. “Everything should just happen seamlessly and invisibly so customers don't have to give that part of our relationship a lot of thought. This allows us to focus on helping them become more efficient in their operations and supporting them in delivering care to their patients.”

McKesson also set up a new distribution center in Seattle, replacing an older facility in Everett, Washington. The company is taking a new approach to its distribution centers that gives them a smaller footprint. The Seattle facility will work in tandem with McKesson's Portland, Oregon distribution center to cross-stock opportunities, building orders in two different facilities but offering a seamless delivery to its customers. By using central-fill facilities as an extension of a retail pharmacy, they can pass along a cost reduction of dispensing to its customers.

Central fill is one of many areas where McKesson is investing in ways to improve its pharmacy customers' capabilities.

The company also offers solutions for how to better handle administrative burdens and methods for building clinical offerings. With its recent acquisitions of CoverMyMeds, a leader in healthcare technology, retail pharmacies can now offer electronic prior authorizations as well as real-time benefits check. Tyler said that McKesson is focused on increasing its pharmacy customers' access to specialty drugs for patients. Some of the administrative tasks required for these drugs is automated by CoverMyMeds, while helping facilitate better communication between various stakeholders.

“We firmly believe that health care is fundamentally a human-dependent industry. Pharmacy and pharmacists will always be an important part of that, and we can provide other capabilities – whether it's digital capabilities or services – that can be provided in a store setting, Tyler said. “We know the model will continue to evolve as patient and customer expectations continue to evolve, and we want to be at the forefront of leading those efforts on behalf of our pharmacy customers.”

Big Pharma Testifies on Capitol Hill Over Drug Pricing

(Source: An article by Jessica Merrill for Scrip and an article by Christopher Rowland for the Washington Post)

Seven of the world's largest pharmaceutical manufacturers testified at a U.S. Senate Finance Committee hearing on drug pricing on February 26th, but the tone was more collaborative than confrontational, giving the pharma industry reason to be cautiously optimistic. The three-hour hearing involved testimony from executives from Pfizer Inc., AstraZeneca PLC, Sanofi, Johnson & Johnson, Bristol-Myers Squibb, Merck & Co., and AbbVie Inc.

Several of the leaders included ideas for lowering drug prices in their opening statements, with standout testimony coming from AstraZeneca CEO, Pascal Soriot, who offered four clear-cut proposals, including rebate reform, out-of-pocket caps for Medicare patients, a system supportive of value-based agreements, and fostering a healthy biosimilar market. These proposals were echoed by several others during testimony.

Surprisingly, the most challenging lines of questioning came from Republican senators, particularly Sen. Bill Cassidy (R-La.) whom at one point seemed to be advocating in favor of direct Medicare negotiations. Other areas that were covered were the high cost of drug prices in the U.S. as compared with other countries, as well as drug patents and how they affect launches of biosimilars in the U.S. versus Europe.

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June. It is proposing to amend the Health Sciences Council's subcommittee pharmaceuticals and medical devices regulations by abolishing the inclusion of package inserts and instead provide the information through “electronic means.” The proposed amendment stemmed from growing concern among pharmaceutical wholesalers that the task of providing paper-based labels on “first deliveries” is physically impossible. According to wholesalers, the rule is unrealistic because staffers who actually deliver the products cannot open and check the actual products until they are delivered, according to a representative from the **Federation of Japan Pharmaceutical Wholesalers Association (JPWA)**.

(Sources: Company Press Releases, Pharma Japan, Pharma Times, Scrip and Yahoo Finance)