Delivering life-saving treatments and end-to-end traceability for patient safety

Johnson & Johnson Supply Chain (JJSC) is comprised of more than 63,000 professionals worldwide who support the global supply chains of Johnson & Johnson's business segments—from planning and sourcing to manufacturing, logistics and deployment. When delivering medicines to healthcare providers and patients around the world, JJSC in Germany is leading the way to ensure the authenticity and safety of these drugs with its serialisation programme, supporting the European Union (EU) Falsified Medicines Directive. Using GS1 standards as a foundation, JJSC is confident that compliance can be simplified as more and more European countries adopt the GS1 common language of business.

Global compliance strategy

Dirk Van den Wouwer, EMEA End-to-End Traceability Leader with JJSC, is responsible for the serialisation and traceability programme of all products manufactured in the EMEA region (Europe, Middle East and Africa) and distributed throughout the world.

"Since we serve the global marketplace, we must comply with all of the different regulations in the different regions and countries—something that could be quite complex," says Van den Wouwer.

As the EMEA regional lead for the global serialisation and traceability programme, Van den Wouwer is making sure that all JJSC production and distribution sites including processes and systems, are ready for the EU Falsified Medicines Directive (FMD) 2019 deadline.

An integral part of the company's global compliance strategy is GS1 standards.

"We are using GS1 standards, a combination of serial numbers and GTINs (GS1 Global Trade Item Numbers) in barcodes to uniquely identify each product," says Van den Wouwer. "This allows us to track and trace the packaged product, from our manufacturing site to any patient, in any country across the globe."

Simplifying complexity

Van den Wouwer explains why JJSC has chosen to use GS1 standards globally. "In the healthcare industry, supply chains have become increasingly complex and vulnerable to falsified medicines. We have invested and continue to invest in standard operating procedures, common platforms and GS1 standards to help us simplify processes—to speak 'one business language' in our multi-national environment. The more global the healthcare supply chain becomes, the more it is a 'must' to work with standards."

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Complexity is also a growing challenge in healthcare provider environments. The use of specialised drugs for targeted treatments of specific diseases has meant an increase in the number of medicines used —and an increase in the exposure for falsification. To keep patients safe, regulations across the globe like the EU's FMD are requiring the serialisation of drugs.

Yet, Christiane Puellen-Lanckohr, Director of Business Quality for Janssen Germany, the pharmaceutical company of Johnson & Johnson in Germany, advises "implementing the FMD regulation across different countries with different interpretations of the legislation can be complicated." She says, "Compliance could be greatly simplified if one set of standards was accepted and used in the various countries in which we do business."

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Ensuring interoperability

Indeed, without a common approach, managing the labelling and packaging of drugs that are bound to as many as 32 countries in the EU, European Economic Area (EEA) and Switzerland could be costly and time-consuming.

"This is why we—across JJSC—are using GS1 standards to provide a common foundation for product identification and traceability," says Van den Wouwer. "This will help us improve efficiencies, lower costs, reduce errors and ultimately, save time when meeting regulatory deadlines."

While GS1 standards are global, some countries have their own national numbers used in their reimbursement systems. To support interoperability, GS1 has created a standard that allows it to capture that national number in addition to the GTIN in the barcode. "In Germany, we had the option to use a GS1 compliant number or another in-country alternative," comments Van den Wouwer. "When establishing our traceability pilot, we chose the GS1-compliant number since it works within the GS1 system of standards, simplifying our cross-border business operations."

Marian Omtzigt who is the Serialisation Business Process Manager EMEA adds, "Using GS1 standards makes good business sense. There was no need to adjust or modify our systems or packaging processes, which saved us significant costs and time. The national number and GTIN are 'encoded' in the same barcode so that both can be read with a single scan to identify the package as it travels through the supply chain—a benefit for us and our customers."

Today, the majority of worldwide countries are accepting and using the GS1 standards. "As we rollout traceability across the globe, having common standards in place will help us stay on track and schedule," says Van den Wouwer. "Furthermore, we will be able to implement within a relatively short timeframe the mandate to publish our serialised GTINs in the European Hub system."

Learning early with pilots

In support of the FMD, JJSC took a leadership role in 2011 to work with the European Federation of Pharmaceutical Industries and Associations (EFPIA) and other innovation-based pharmaceutical manufacturers to help with the creation of the European Stakeholder Model (ESM), ensuring as such the design, development and establishment of the European end-to-end verification system that enables medicines to be verified at the point of dispensing.

JJSC was also instrumental during the vendor selection process, helping to establish a quality system for the European Medicine Verification Organisation (EMVO) and European Hub.

At the end of 2015, JJSC tested its end-to-end serialisation and verification process in Germany. The German pilot focused on six products, produced in two manufacturing plants.

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Serialised GTINs encoded in barcodes were applied to packages, published in the European Hub, Europe's centralised data distribution system, and then downloaded to securPharm, Germany's national medicines verification system.

As packages arrived in the 400 pharmacies that were part of the pilot, they were successfully authenticated via the European Medicines Verification System.

"With this pilot in Germany, we proved that our system and standards work from end to end," Van den Wouwer explains. "We built close partnerships with the European Medicine Verification Organisation and those who manage securPharm. By piloting the process, it helped us learn 'on the go' so that we can share and leverage our experiences in the next pilots that we will conduct."

One notable lesson learned is the need to publish master data in the European Hub system with the expectation that master data requirements may differ from country-to-country in the future. With this in mind, JJSC is now planning the next pilot, to include more products in more sites, and with master data requirements as a pilot priority.

"With growing confidence and plenty of lessons learned, we will continue to implement this new serialisation process 31 more times before 2019," says Van den Wouwer.

Planning with confidence

While this may sound overwhelming, Van den Wouwer points out that it doesn't have to be.

If a single standard was applied across all countries, JJSC could start immediately adjusting its systems and artwork for all products and packaging to accommodate a highly efficient rollout of the new FMD-compliant serialisation process.

Yet, the FMD framework allows for small differences regarding the type of unique identifier, which means necessary artwork changes and other actions cannot truly begin until those decisions are in place for a specific country.

Even with this uncertainty, Van den Wouwer and his team are confident in meeting the 2019 deadline. "We have plans in place on how to move forward with our systems, processes and retrofitting the different lines in our manufacturing sites. Yet, as critical regulatory information for changes such as artwork move further out in time, this 'snowplow effect' could turn a relatively straightforward, standards-based process into a more and more complex one."

In its pilot, JJSC proved that its system and GS1 standards worked to provide traceability from manufacturing to pharmacy.

"The value of GS1 standards extends far beyond compliance—simplified processes, lower cost of ownership, shared systems and quality data."

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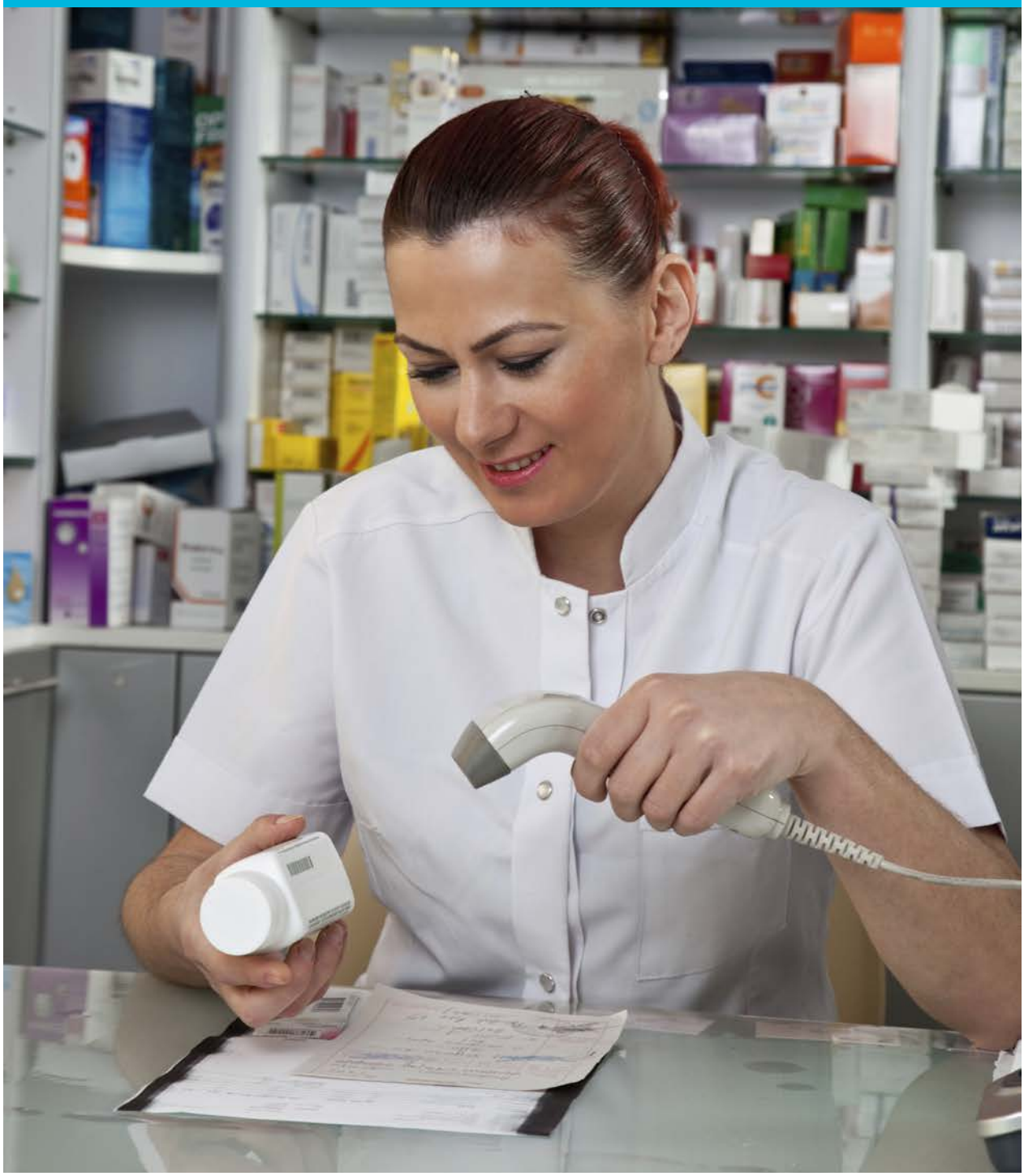

Ready for the world

As new regulations emerge in other parts of the world, JJSC will be ready with GS1 standards.

“At JJSC, we have built an enterprise-wide set of capabilities, leveraging GS1 standards for worldwide regulatory compliance,” says Van den Wouwer. “As regulations evolve across the globe, we will be able to more easily and quickly report to regulatory authorities.”

At the same time, Van den Wouwer stresses that “the value of GS1 standards extends far beyond compliance—simplified processes, lower cost of ownership, shared systems and quality data.”

“Perhaps the biggest advantage is the common language that enables a common system for interoperability across companies, industries and even countries,” explains Van den Wouwer. “With the FMD as a backdrop, I’m confident that we will come together in Europe with patient safety as a common goal and GS1 standards as a common language.”

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About the Authors

Dirk Van den Wouwer *is the lead for EMEA serialisation and traceability for JJSC. With more than 25 years of experience, Van den Wouwer has held various leadership positions in supply chain management, program management, global planning and business process development. He holds masters degrees in Engineering with specialisation in Operations Management and Logistics.*

Christiane Puellen-Lanckohr *is a pharmacist and has worked in the pharmaceutical industry for more than 23 years, primarily in Quality with experience in Pharmacovigilance, Regulatory, Supply Chain and Commercial. As the director of Business Quality with Janssen Germany, she is committed to ensuring quality practices are part of the company’s operations for targeted outcomes.*

Marian Omtzigt *is the Serialisation Business Process Manager EMEA with JJSC. She works with the JJSC Brand Protection and Supply Chain Visibility organisations, engineering, manufacturing and distribution centres to influence and direct Johnson & Johnson’s global serialisation strategy.*

About Johnson & Johnson Supply Chain

Johnson & Johnson Supply Chain encompasses four segment supply chains (Pharmaceuticals, Consumer Products, Medical Devices, and Diabetes & Vision Care) that cover planning, sourcing, internal and external manufacturing, Customer Logistics Services and the Supply Chain Strategy and Deployment.

Additional enterprise-wide functions that are part of Johnson & Johnson Supply Chain include Quality & Compliance, Environment, Health, Safety & Sustainability and Engineering & Technical Operations. www.jnj.com

About GS1 Healthcare

GS1 Healthcare is a global, voluntary user community bringing together all healthcare supply chain stakeholders, including manufacturers, distributors, healthcare providers, solution providers, regulatory bodies and industry associations. The mission of GS1 Healthcare is to lead the Healthcare sector to the successful development and implementation of global standards by bringing together experts in Healthcare to enhance patient safety and supply chain efficiencies. GS1 Healthcare members include over 70 leading Healthcare organisations worldwide.

For more information about GS1 Healthcare, please visit www.gs1.org/healthcare

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