

IBM, KPMG, Merck and Walmart to collaborate as part of FDA's program to evaluate the use of blockchain to protect pharmaceutical product integrity

The FDA pilot program explores innovative and emerging approaches for the tracing and verification of prescription products

ARMONK, N.Y., NEW YORK, KENILWORTH, N.J., and BENTONVILLE, Ark., June 13, 2019 /PRNewswire/ -- IBM (NYSE: [IBM](#)), KPMG, Merck (NYSE: MRK), and Walmart (NYSE: WMT) today announced that the companies have been selected by the United States Food and Drug Administration (FDA) to be included in a program in support of the U.S. Drug Supply Chain Security Act (DSCSA) that addresses requirements to identify, track and trace prescription medicines and vaccines distributed within the United States.

The program is intended to assist drug supply chain stakeholders, including FDA, in developing the electronic, interoperable system that will identify and trace certain prescription drugs as they are distributed within the United States.

"Our supply chain strategy, planning and logistics are built around the customers and patients we serve," said Craig Kennedy, Senior Vice President, Supply Chain, at Merck, which is known as MSD outside the U.S. and Canada. "Reliable and verifiable supply helps improve confidence among all the stakeholders—especially patients—while also strengthening the foundation of our business."

Each company brings unique expertise to the project, which will create a shared permissioned blockchain network that allows real-time monitoring of products. The proposed network is intended to help reduce the time needed to track and trace inventory; allow timely retrieval of reliable distribution information; increase accuracy of data shared among network members; and help determine the integrity of products in the distribution chain, including whether products are kept at the correct temperature.

"With successful Blockchain pilots in pork, mangoes and leafy greens that provide enhanced traceability, we are looking forward to the same success and transparency in the biopharmaceutical supply chain," said Karim Bennis, Walmart's Vice President of Strategic Planning and Implementation, Health and Wellness. "We believe we have to go further than offering great products that help our customers live better at everyday low prices. Our customers also need to know they can trust us to help ensure products are safe. This pilot and U.S. Drug Supply Chain Security Act requirements will help us do just that."

Blockchain is designed to establish a permanent record and may be integrated with existing supply chain and traceability systems.

"Blockchain could provide an important new approach to further improving trust in the biopharmaceutical supply chain," said Mark Treshock, IBM Global Solutions Leader for Blockchain in Healthcare & Life Sciences. "We believe this is an ideal use for the technology because it can not only provide an audit trail that tracks drugs within the supply chain; it can track who has shared data and with whom, without revealing the data itself. Blockchain has the potential to transform how pharmaceutical data is controlled, managed, shared and acted upon throughout the lifetime history of a drug."

IBM, KPMG, and Walmart, the largest retailer in the U.S., have extensive experience in implementing blockchain solutions to help enhance the safety and traceability of products. Increasingly, customers are requesting more detailed information about products.

"Blockchain's innate ability within a private, permissioned network to provide an 'immutable record' makes it a logical tool to deploy to help address DSCSA compliance requirements," said Arun Ghosh, KPMG Blockchain Leader. "The ability to leverage existing cloud infrastructure is making enterprise blockchain increasingly affordable and adaptable, helping drug manufacturers, distributors and dispensers meet their patient safety and supply chain integrity goals."

The pilot project is scheduled to be completed in fourth quarter of 2019, and results are expected to be published in an FDA DSCSA program report. At that time, the project's participants will evaluate next steps.

About the DSCSA pilot program

DSCSA was enacted by Congress on Nov. 27, 2013. It outlines steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States. The DSCSA pilot project program is intended to help identify and evaluate the most efficient processes to comply with and apply drug supply chain security requirements. The program will aid in identifying attributes the system will need for enhanced product tracing and verification, as well as electronic means to share the information. The FDA will be sharing new approaches considered through this program with the broader drug supply chain community on the agency's website. Our goal is to ensure that all parties can be apprised of the program's progress and take advantage of any shared learning.

About IBM Blockchain

IBM is recognized as the [leading enterprise blockchain provider](#). The company's research, technical and business experts have broken barriers in transaction processing speeds, developed the most advanced cryptography to secure transactions, and are contributing millions of lines of open source code to advance blockchain for businesses. Since 2016, IBM has worked with hundreds of clients across financial services, supply chain, government, retail, digital rights management and healthcare to implement blockchain applications, and operates a number of networks running live and in production. The cloud-based IBM Blockchain Platform delivers the end-to-end capabilities that clients need to quickly activate and successfully develop, operate, govern and secure their own business networks. IBM is an early member of Hyperledger, an open source collaborative effort created to advance cross-industry blockchain technologies. For more information about IBM Blockchain, visit <https://www.ibm.com/blockchain/> or follow us on Twitter at @ibmblockchain.

About KPMG

KPMG LLP is the independent U.S. member firm of KPMG International Cooperative ("KPMG International"). KPMG International's independent member firms have 207,000 professionals in 153 countries and territories. Learn more at www.kpmg.com/us. The KPMG and IBM Alliance brings together IBM's technology and KPMG's advisory and tax services, combining in-depth industry knowledge of key business issues to deliver innovative solutions for clients. Visit the [KPMG and IBM alliance website](#) for more information. Some or all of the services described herein may not be permissible for KPMG audit clients and their affiliates or related entities.

About Merck

For more than a century, Merck, a leading global biopharmaceutical company known as MSD outside of the United States and Canada, has been inventing for life, bringing forward medicines and vaccines for many of the world's most challenging diseases. Through our prescription medicines, vaccines, biologic therapies and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to health care through far-reaching policies, programs and partnerships. Today, Merck continues to be at the forefront of research to advance the prevention and treatment of diseases that threaten people and communities around the world – including cancer, cardio-metabolic diseases, emerging animal diseases, Alzheimer's disease and infectious diseases including HIV and Ebola. For more information, visit www.merck.com and connect with us on Twitter, Facebook, Instagram, YouTube and LinkedIn.

About Walmart

Walmart Inc. (NYSE: WMT) helps people around the world save money and live better - anytime and anywhere - in retail stores, online, and through their mobile devices. Each week, over 275 million customers and members visit our more than 11,300 stores under 58 banners in 27 countries and eCommerce websites. With fiscal year 2019 revenue of \$514.4 billion, Walmart employs more than 2.2 million associates worldwide. Walmart continues to be a leader in sustainability, corporate philanthropy and employment opportunity. Additional information about Walmart can be found by visiting <http://corporate.walmart.com>, on Facebook at <http://facebook.com/walmart> and on Twitter at <http://twitter.com/walmart>.

Forward-Looking Statement of Merck & Co., Inc., Kenilworth, N.J., USA

This news release of Merck & Co., Inc., Kenilworth, N.J., USA (the "company") includes "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company's management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline products that the products will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company's 2018 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (www.sec.gov).

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