Government initiatives

Indian government implements track and trace system for pharmaceuticals

For continued confidence in exported pharmaceuticals from India, the government wanted a mechanism by which patients and regulators worldwide could verify their information. With this primary objective, the Indian government's National Informatics Centre (NIC) designed the Drug Authentication and Verification Application (DAVA) based on GS1 standards.
GS1 standards make it possible to uniquely identify, capture and share important information on these pharmaceuticals with regulators and patients, thereby further strengthening India's reputation as a leading producer of quality and safe drugs.

By Anil K. Sinha

Background

The Indian pharmaceutical industry is the third largest in the world in terms of volume, accounting for 10 percent of the world's production. India's total export of pharmaceuticals in 2015-2016 was about US $18 billion. With exports to more than 200 countries, India is the world leader in the production of generic drugs and vaccines. Every third dose of vaccine administered anywhere in the world comes from an Indian manufacturing facility.

The challenge of protecting image and safety

To maintain and grow its leadership position as the world's leading manufacturer of pharmaceuticals, the Indian government wanted to take proactive measures to ensure the safety and security of pharmaceuticals produced and exported from the country.

This strategy was adopted to protect India's brand image as a producer of safe and quality drugs amid growing concerns of regulators and patients worldwide regarding the general increase of counterfeit drugs. It was also a means to prevent counterfeits from ever entering the supply chain and in the event that they did, then to quickly identify the counterfeit.

With these objectives the government wanted to:

- Build a mechanism by which it could have visibility on all drugs produced and exported from the country by the estimated 2,000 large, medium and small manufacturers.
- Provide regulators and patients across the world a means to verify the product details, including at which Indian manufacturing facility the pharmaceutical was produced.

Given the size of the Indian pharmaceutical industry, one of the biggest challenges for the government was to develop a solution that would provide real-time visibility to all manufactured and exported drugs in the country.

In order to provide such information to a global audience (regulators, importers and patients), an infrastructure, which was robust and easy to access by thousands of manufacturers including small and medium enterprises to facilitate information flow was needed.

The solution required accurate identification of all pharmaceuticals manufactured for exports and the capture of information related to its

production, batch number, and expiry date and more, which could then be authenticated globally.

Traceability with GS1 standards

A traceability system based on GS1 standards proved an ideal solution for the Indian government. It not only gave the ability to accurately identify pharmaceuticals at various packaging levels, but it also provided the ability to collect and store product information that would help identify from which manufacturing unit it came.

An added advantage in using GS1 standards in the traceability solution was that it gave Indian manufacturers the ability to comply with regulatory requirements of different importing countries such as the U.S. Food and Drug Administration's (FDA) unique device identification of medical devices (UDI) regulation, Drug Supply Chain Security Act (DSCSA) requirements and the European Union Falsified Medicine Directive. Use of GS1 standards also increased the possibility of a manufacturer's entry into these markets, if it didn't previously do so.

The traceability system was named DAVA, which means "medicine" in the Indian language (and is also the abbreviation for Drug Authentication and Verification Application). This system has made it possible to gain real-time visibility to pharmaceuticals produced and exported from India.

DAVA relies on the use of Global Trade Item Numbers (GTINs) plus serial numbers by manufacturers to easily identify the various packaging hierarchy levels of pharmaceuticals such as primary, secondary and tertiary (when a trade item) levels.

While some information like the brand name is captured in the system, the information in the table below is captured through GS1-128 and GS1 DataMatrix barcodes.

GS1 standards used by DAVA

Packaging Level	Barcode Symbology	Encoded Information
Primary Level Innermost level of packaging, which is in direct contact with the product (e.g., medicine strip, vial, single therapy kit)	GS1 DataMatrix	• GTIN • Expiry date • Batch number • Unique serial number *(Use of unique serial number at this packaging level is optional.)*
Secondary Level Packaging level containing primary level packages (e.g., mono-cartons)	GS1 DataMatrix or GS1-128	• GTIN • Expiry date • Batch number • Unique serial number
Tertiary level Outermost level of packaging containing secondary and other intermediate packages that may be used as either a trade item or a logistic unit meant for transport (e.g., cartons, pallets, shipments)	GS1-128	When a trade item: • GTIN • Expiry date • Batch number When a logistics unit: • Serial Shipping Container Code (SSCC)

Implementation is being rolled out in phases, starting with large and medium manufacturers and followed by small-scale manufacturers. Implementation of the barcode labelling and marking requirements for the secondary and tertiary-level packaging has been mandated, while barcoding at the primary level is optional.

Manufacturers maintain parent-child relationship information, (i.e., which product is in which secondary pack and in which tertiary pack) so that at any point it's possible to identify the secondary packs of a tertiary unit and the primary pack of a secondary unit. This information is essential to establish pedigree of the product in order to provide its authentication.

Manufacturers and exporters directly upload data to DAVA after production and before the consignment leaves their manufacturing facilities. The accuracy, completeness and timely upload of the data is their responsibility.

DAVA is also integrated with a mobile application, which empowers customs officials, regulators, importers and patients to authenticate product information of pharmaceuticals by simply scanning the barcode on any of its packaging levels. When a product's barcode is scanned, all the information associated with the product is retrieved from the DAVA system. This gives the user the opportunity to authenticate the product.

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Increasing efficiencies and guarding against counterfeits

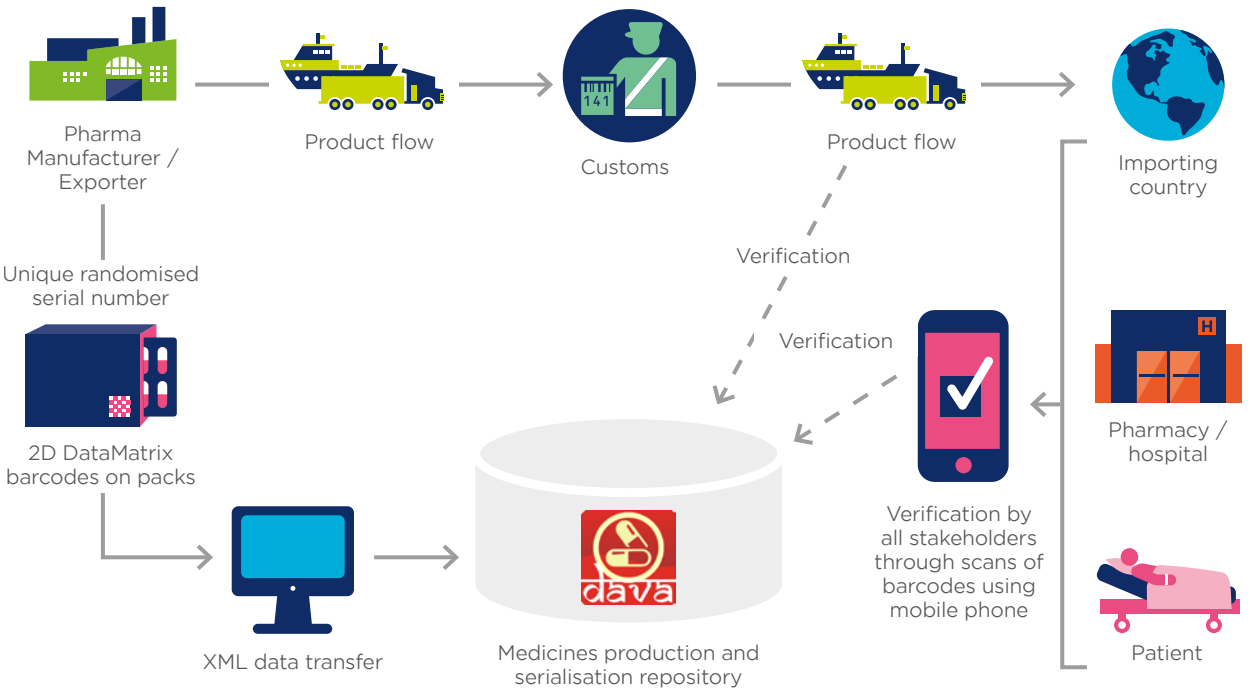
The main goal of the Indian authorities was to provide real-time information online to authorities and patients of pharmaceuticals manufactured in India.

By implementing DAVA, India has achieved that and more. More than 2,000 pharmaceutical export manufacturers will be estimated to upload production level data for millions of drugs to DAVA over the next months.

Despite its recent rollout, the government and pharmaceutical industry are already seeing some benefits. Once fully implemented, DAVA enabled by GS1 standards is expected to deliver the following:

- Pharmaceutical consignments are expected to move through customs both in India and at the importing country much faster than it does today, because consignments can be quickly inspected by scanning barcodes and validating them against the data available in DAVA.

How DAVA works



- Indian pharmaceutical manufacturers will be able to improve the accuracy of their dispatch processes and enable efficient and automated FIFO (first in, first out) management.
- Indian pharmaceutical manufacturers will have a competitive edge in international markets for being able to comply with various global and national regulations and buyers' requirements.
- Global confidence in India's brand image as a safe producer of pharmaceuticals will be protected.
- Indian regulators will be able to fight any false counterfeit allegations, if and when required.
- Consumers will be empowered to authenticate and be protected against health and safety risks associated with counterfeits.

The Asia-Pacific Council for Trade Facilitation and Electronic Business (AFACT), under the United Nations Centre for Trade Facilitation and Electronic Business (UN/CEFACT), awarded the e-ASIA Award to DAVA, as the best trade facilitation system in the region.

The way forward

With the success of this project, the government of India plans to expand this system to capture information on drugs that are manufactured for the domestic market as well. The domestic rollout may have added capabilities such as tracking the movement of pharmaceuticals from point-of-manufacture to point-of-sale by capturing all distribution points and stakeholders in the supply chain.

In addition to helping prevent counterfeits and giving patients the ability to authenticate drugs, the added capabilities will help government officials monitor the availability of stocks in an area or with a wholesaler or retailer at any given point in time. This information would be extremely valuable to mobilise drugs to a region during epidemics or disease breakouts.

Such a rollout will also make drug recalls easier and more efficient and improve overall patient safety by ensuring that only safe and genuine drugs make their way to patients.

About the Author

Anil K. Sinha *is the Deputy Director General of the National Informatics Centre and the Mission Leader for the eTRADE project for the Government of India. With over 30 years of experience in Information Technology and E-Governance, Mr. Sinha has been instrumental in the introduction of ePayments for government businesses. He has also played a key role in the implementation of several key projects such as eDelivery of Services, which includes the automation of licensing processes, integration of digital signatures, implementation of Electronic Bank Realisation Certificates (eBRC), and DAVA among others. As the head for the IT division of various departments under the Ministry of Commerce, Mr. Sinha has been responsible for policy changes as well.*

About DAVA and the National Informatics Centre

The National Informatics Centre (NIC) is responsible for the design, development and implementation of the Drug Authentication and Verification Application (DAVA) system on behalf of the Director General of Foreign Trade (DGFT). Based on GS1 standards, DAVA enables manufacturers to share important information on these pharmaceuticals with regulators and patients, thereby further strengthening India's reputation as a leading producer of quality and safe drugs. NIC is the premier science and technology organisation of India's Union Government in informatics services and information-and-communication-technology (ICT) applications. NIC is a part of the Indian Ministry of Communications and Information Technology's Department of Electronics & Information Technology and has played a pivotal role in steering e-governance applications in governmental departments at national, state and district levels, enabling the improvement in, and a wider transparency of, government services.

Other project stakeholders include the Ministry of Commerce and Industry, Ministry of Health & Family Welfare, Directorate General of Foreign Trade (DGFT), Pharmaceutical Export Council of India (Pharmexcil) and GS1 India.

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