

# India

## Serum Institute of India: Implementing UNICEF guidelines for distribution of COVID vaccines

### Challenge

Serum Institute of India needed a to comply with the UNICEF mandate for seamless delivery of vaccine to various parts of the world.

### Approach

SII adopted GS1 standards to create a traceability system for all COVID vaccines, meant for exports.



Increased visibility of vaccines in supply chain



Real-time monitoring and recording of vaccine temperature



Enables vaccine authentication at point of vaccination



Swift and targeted recalls, whenever needed

### Supplying the world with COVID vaccines

Serum Institute of India (SII) is one of the world's largest vaccine producers when it comes to manufacturing and supplying the COVID vaccines both for India and globally. It needed a solution that ensured compliance with the UNICEF mandate for seamless delivery of vaccine to various parts of the world. The directive required that each vaccine should be uniquely identified to prevent falsified vaccine. SII needed to use global standards to effectively track and trace COVID vaccines throughout the supply chain—from production to healthcare providers.

### Creating a traceability system

With support of GS1 India, SII adopted global standards as it enabled them to fulfil the UNICEF mandate for supplying vaccines to other countries. This required a GS1 standards-based track and trace system to be set up for all COVID vaccine exports.



To provide end-to-end traceability, SII started with the implementation of batch-level traceability. Over time, it moved to case-level traceability with the use of serialised barcodes on intermediate secondary packaging and Serialised Shipping Container Codes (SSCC) on tertiary packages of COVID vaccine supplies. By scanning serialised barcodes, the information captured included the vaccine's Global Trade Item Number® (GTIN®), batch number, serial number and expiry date.

*“The adoption of GS1 standards not only enabled us to fulfil the UNICEF directive for traceability purposes but also for internal process optimisation and ensure targeted recalls, if required. GS1 India supported us during the whole implementation phase. We appreciate the support received from GS1 India. A long-standing relationship with GS1 India helped us adopt traceability requirements of UNICEF and other importing countries.”*

**Dr. Sunil Gairola,**  
Executive Director, Serum Institute of India

To support implementation, GS1 India conducted various workshops and webinars to ensure a smooth transition of processes. This also included technical support to manage country-specific regulations and regulatory requirements in domestic supplies to various State Governments.

*“Tracking each batch of vaccines as it moves through the supply chain is important to secure the chain and ensure patient safety. GS1 standards help in ensuring safety and trust in COVID vaccines supply.”*

**Mr. Sachidanantham Swaminathan**  
CEO, GS1 India



### Benefits realised by implementing GS1 standards

- Ensures increased visibility of the vaccines in the supply chain in real-time to efficiently manage inventory and distribution
- Enables real-time monitoring and recording of temperature to ensure that the right temperature is maintained throughout the supply chain – storage as well as transportation
- Ensures effective patient coverage, without wastage and pilferages
- Enables authentication of the vaccine at the point of inoculation
- Enables swift and targeted recalls, whenever required
- Enables a common platform for various regulatory bodies across the globe to work collaboratively to deliver vaccines





## Future roadmap

With the requirement of global standards gaining precedence for track and trace of vaccines, SII has plans to barcode vaccines meant for domestic supplies as well.

### About the authors



**Dr. Sunil Gairola**  
EVP- packaging,  
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Sunil Gairola, Ph.D, is the Executive Director of Serum Institute of India Pvt. Ltd. He has more than 38 years of experience in quality control of vaccines, adjuvant development, and managing quality control-related activities, and has significantly contributed towards the development and calibration of national reference Standards for vaccines and antisera. He is by training a microbiologist and joined SIIPL in 1994. Expertise in characterization of bacterial, viral, recombinant antigens using advanced analytical tools and implementation of newer technologies in quality control of vaccines. Leads a team of more than 400 Scientists. Collaborator to international initiatives of WHO, NVI, NIBSC, EDQM, and PATH, aimed at the harmonization of regulatory requirements, the establishment of international standards, and the development of quality control release assays for immunobiologicals. Served as IP Expert committee for many years and Member, Scientific Body. Also member to expert committee/panel of USP. Published research papers in National and International journals. Attended many National and International Conferences as well as WHO Consultations on scientific topics.



**Mr. Sachidanantham Swaminathan**  
CEO, GS1 India

Mr. Swaminathan has been actively engaged with several government and industry projects related to track & trace, recall and supply chain management for adoption of global standards and best practices, which facilitate unique and universal product identification and authentication, and information exchange of product data between trading partners.

He has 29 years of experience across Automatic Data Capture Industry and software products & services sector in varied responsibilities incl. channel development, supply chain management, sales/marketing and project management for domestic and international markets. Mr. Swaminathan is an Engineering graduate in Computer Science from Bharathiar University and alumnus of IIFT Delhi.

## About the organisation



Serum Institute of India Pvt. Ltd. is one of the world's largest vaccine manufacturers by the number of doses produced and sold globally.

Vaccines manufactured by the Serum Institute are accredited by the World Health Organization, Geneva and are being used in around 170 countries across the globe in their national immunization programs, saving millions of lives.

The Serum Institute of India (SII) and UNICEF have entered into a long-term supply agreement for the AstraZeneca/Oxford and the Novavax vaccines. UNICEF plays a key role in immunisation campaigns worldwide under the COVAX program. COVAX is co-led by the Coalition for Epidemic Preparedness Innovations (CEPI), Gavi, and the World Health Organization (WHO), alongside key delivery partner UNICEF. It aims to accelerate the development and manufacturing of COVID-19 vaccines and to guarantee fair and equitable access for every country in the world.

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