India Track and Trace System for Export of Pharmaceuticals and Drug Consignments

Regulatory Update
August 2020

Regulatory Agency	India Ministry of Commerce and Industry, Department of Commerce, Directorate General of Foreign Trade (DGFT)
Regulation Name or System Name	Track and Trace System for Export of Pharmaceuticals and Drug Consignments
Compliance Dates	Drugs can be exported from India only if both the secondary and tertiary packaging carries the specified serialized barcode and the corresponding data is uploaded to the central portal (www.iVeda-india.in). Serializing the primary level is optional at this time.
	In Early 2016 the DGFT issued new deadlines for serialization and the collection and reporting of aggregation data based on the size of the exporting company, split between small scale industries (SSI) and non-SSI companies.
	*"All drugs manufactured by non SSI units with manufacturing date on or after [**April 1, 2016**] and all drug manufactured by SSI units with manufacturing date on or after [**April 1, 2017**] can be exported only if both tertiary and secondary packaging carry barcoding as applicable and the relevant data as prescribed by DGFT is uploaded on the Central Portal."*
	On April 13, 2018 DGFT issued Public Notice #58/2018 indicating that they were finding too many drugs being exported that did not have corresponding data uploaded into the Central Portal. From that date on, those drugs were to be returned to the manufacturer and would not be allowed to be exported until the data is uploaded.
	However, within weeks the Commerce Ministry acknowledged that the DAVA portal has technical problems. They announced a delay in the serialization and the data upload requirements until November 15, 2018 to give the National Information Center (NIC) time to fix the problems and ensure smooth operation. But then on November 1, 2018 the Minister of Commerce and Industry announced that they would extend that date until January 7, 2019. This date continued to be pushed out through 2019.

	In early 2020 the Ministry of Commerce indicated that the DAVA portal will be replaced with a new portal and repository. On March 30, 2020 the DGFT published Public Notice #66 /2015-2020 that pushed the deadline for uploading data to the iVeda portal to October 1, 2020 for both SSI and non-SSI companies. As of July 25, 2020, companies are asked to begin uploading all data to the iVeda portal for production since June 1, 2020.
Applies to	Drug manufacturers who have manufacturing and/or packaging facilities within India, and who export drugs to any other countries. However, if the target country already has a different drug serialization requirement that conflicts with that which is specified by the DGFT, *companies may apply for a waiver for that product*.

Primary Packaging
(packaging which is in direct physical contact with the active ingredient)

Proposed Barcode Symbology	Linear, or 2D Datamatrix following GS1 standards
Proposed Barcode Contents	Product code (use of the GS1 GTIN is now optional), Serial Number, Lot Number, Expiration Date.
Serial Number Randomization	No
Serial Number Reuse	Not specified
Human Readable Expiry Date Format	"YYMMDD"
Barcode Data Encoding	GS1 Standard
Barcode notes	**The bar code labeling at primary level is exempted until further notice**; printing of human readable data will likely be required eventually but can be done on an optional basis until further notice.
Free Samples must be marked?	Not specified
Stickering after manufacturing allowed?	Not specified

Secondary Packaging
(a carton containing one or more primary packs and includes a "mono carton" containing one primary pack)

Proposed Barcode Symbology	Linear, or 2D Datamatrix following GS1 standards
Proposed Barcode Contents	Product code (use of the GS1 GTIN is now optional), Serial Number, Lot Number, Expiration Date.
Serial Number Randomization	No
Serial Number Reuse	Not specified
Human Readable Expiry Date Format	YYMMDD
Barcode Data Encoding	GS1 standard

Barcode notes	In the case of "mono cartons", a manufacturer or exporter shall affix the bar code on mono cartons containing one primary pack on an optional basis until further notice
Free Samples must be marked?	Not specified
Stickering after manufacturing allowed?	Not specified

Tertiary Packaging
(a shipper containing one or more secondary packs)

Barcode Symbology	GS1-128 (linear)
Barcode Contents	Product code (use of the GS1 GTIN is now optional), Lot Number, Expiration Date, GS1 SSCC (SSCC may appear in a separate barcode). See the DGFT Public Notice 52120 I 5-2020 for wording that is difficult to interpret because it uses terminology that contradicts GS1 standards. Manufacturers and exporters should contact DGFT for clarification.

Aggregation Data Capture

Parent-Child Mapping Aggregation Capture?	Yes

Data Exchange

Send Unit Data to Government Repository?	Yes
Send Unit Data to Third-Party Repository?	No
Send Unit Data to Trading Partner?	No
Send Aggregation Data to Government Repository?	Yes
Send Aggregation Data to Third-Party Repository?	No
Send Aggregation Data to Trading Partner?	No

Authentication

Who Offers Data Repository for Authentication?	Government (www.iveda-india.in for now)
Manufacturers Must Register Shipments in Repository?	Yes (exports)
Downstream Trading Partners Must Authenticate on Receipt?	No, optional (future)
Downstream Trading Partners Must Authenticate on Shipment?	No

Government Reporting

Manufacturer Activity Reported?	Yes
Downstream Trading Partner Activity Reported?	No

Challenges

- DGFT requirements deviate from GS1 standards in a couple of ways. The current draft data communications specification requires the "product code" to be 12 digits long "following GS1 standards", but the barcode must contain a GTIN-14, requiring a conversion. In early 2020 the government said that the companies may continue to use GS1 but it is not mandatory, leaving open the question of what would be used in its place. Not sure if this means the use of GS1 standards is optional or if just the use of a GTIN for the product code is optional.

- A document specifies exact definitions of the GS1 "indicator digit" within the GTIN-14. This conflicts with GS1 standards which allow each manufacturer to use these values any way they prefer. This may get in the way of some existing processes.

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About Systech

Systech provides digital product authentication and traceability solutions to combat counterfeiting, prevent diversion and meet regulatory compliance. Built on decades of experience as the leader in pharmaceutical serialization, our comprehensive brand protection suite delivers the real-time insight, actionable product data, digital connectivity and consumer engagement functionality needed to fight supply chain threats.

Global brands across industries rely on us to keep their products authentic, safe and connected—from manufacturing to the consumer's hands. Together we are revolutionizing brand protection!

Regulatory Questions?

Contact us at info@systechone.com or visit us online here.