

INDIAN TRACK AND TRACE SYSTEM EXPORTS



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FDC Limited

FDC LIMITED

- Since 80 years, FDC denotes “FOODS , DRUGS AND CHEMICALS”
- Annual Turnover : 1100 Crores
- Ranked among top pharmaceutical companies in India, featured in prestigious Forbes Asia
- Pioneer in Ophthalmic and Oral Rehydration salts : Electral
- First to bring BLOW-FILL-SEAL technology for ophthalmic in India

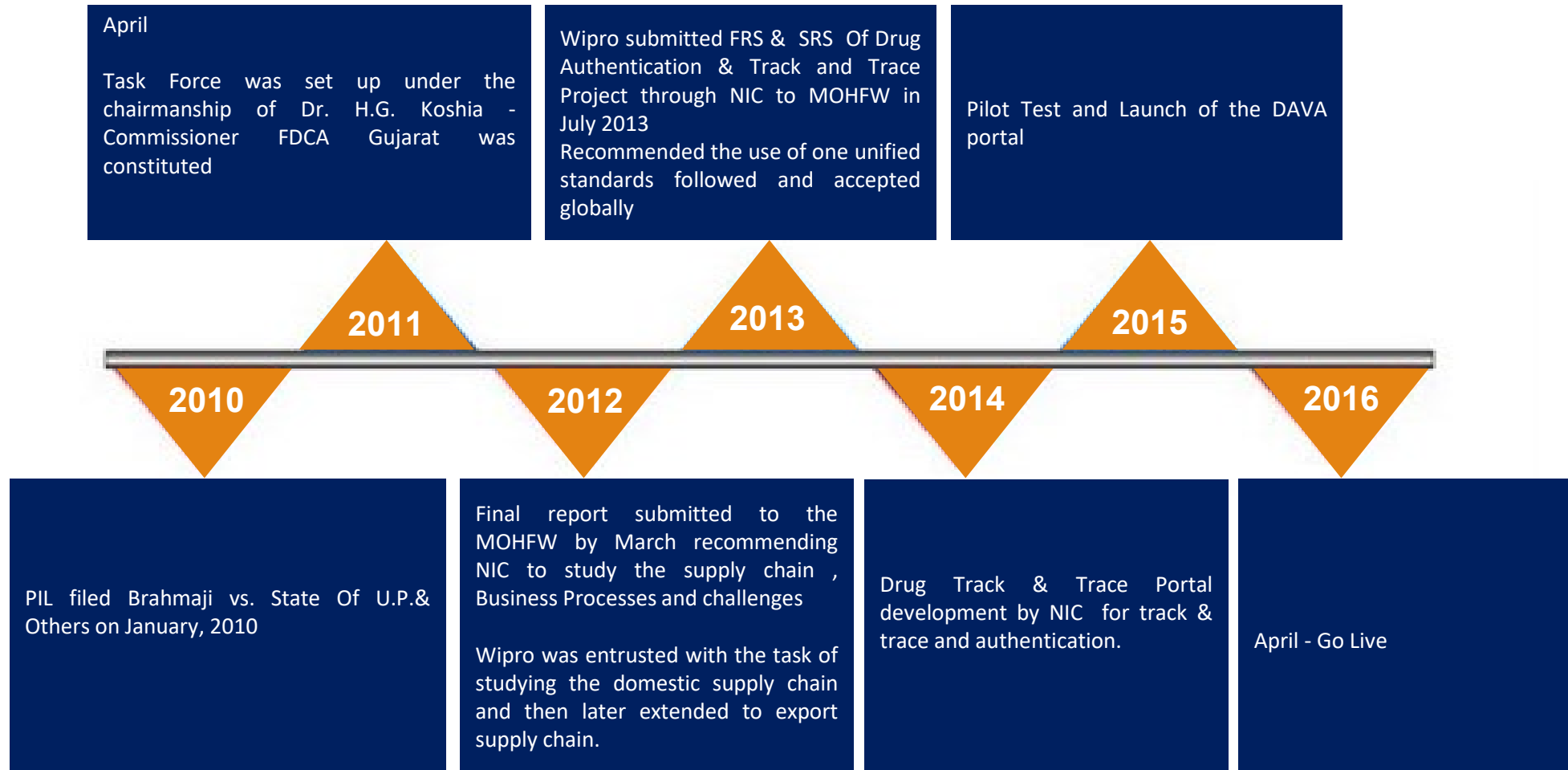


FDC LIMITED : Locations and Compliances



Dosage	<ul style="list-style-type: none"> • Sterile Ophthalmic, Oral solids • Rehydration, Orals (tablets/capsules), API
GMP Certifications	<ul style="list-style-type: none"> • WHO India • USFDA • UKMHRA • TGA Australia • UNICEF • PICs Malaysia • PPB Kenya • MOH Ukraine • Philippines FDA • Thai FDA
Target Markets	<ul style="list-style-type: none"> • Regulated Markets, ROW, Domestic
DGFT Compliance	<ul style="list-style-type: none"> • 100% across all plants

Genesis and Evolution of India Track & Trace Regulation



FDC Journey Towards Track & Trace Compliance

2011

Tertiary Pack Level labelling compliance

2013

Secondary Pack Level barcode compliance


2015

Aggregation and Data upload to track and trace application



It was definitely a hurdle race but we made it on time...

- **Artwork evaluation of all exports of all sites at primary, secondary and tertiary levels**
- **Evaluation of packs to provide sufficient space for the barcoding along with suitability for online printing**
- **Sourcing the software and hardware manufacturers in 2011 as India was one of the first countries to mandate the track and trace.**
- **Identifying the machines suitable to the production lines to match speeds and avoid loss of productivity**
- **Exhaustive trials for smooth operations of printing/scanning and to avoid excess rejections**



**Implementation
Challenges**

- **Preparation of artworks and submission to regulatory department for filing variations- in coordination with the planning department for export order schedule**
- **Manufacturing Line level Impact. Required several line level hardware integration. Some of the lines had to go through an overhaul.**
- **Overcoming the problem of high rejections due to OCR (Optical Character Recognition)**
- **All the lines in-house + several LL/TP which warrant considerable documentation as per cGMP norms**
- **Custom Clearance difficulty as lack of clarity with officials due to multiple extensions and changes during implementation phase**



**Implementation
Challenges**

Secondary Packs : GS1 Datamatrix



Exports accomplished worldwide as per India Track & Trace Regulation



GS1 India Support in this Journey

- **Technical Training : Classroom and Webinar**
- **GS1 India published implementation guideline for ease of implementation**
- **Barcode verification and handholding support with data upload to Track & Trace system**
- **Highly responsive and supportive team who gave timely support vide phone calls, emails to help and resolve on-going issues**

Impact of DGFT mandate on Indian Pharma Industry

- Industry got hands on experience of barcoding, serialization and track and trace since 2011
- Enabled Indian pharmaceutical companies to be ready for the serialization and track & trace requirement for the rest of the world
- Same infrastructure extended by pharma companies which had common lines for ROW and regulated market exports
- The software and hardware providers in India learnt and adapted in the course of implementation of Indian DGFT requirement
- All the groundwork could be started by these providers to meet the requirements of DSCSA - US market and FMD - EU markets
- This led to availability of more vendors for the implementation of DSCSA, FMD and helped in smooth implementation for other markets

