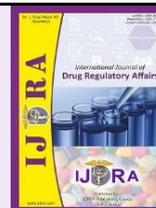


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Review Article

**Good e-Governance: Xtended Licensing, Laboratory & Legal Node (XLN) - An effective tool for Good Regulatory Practice in field of Drugs and Cosmetics Regulation**Zuki Patel^{*a}, Shrikalp Deshpande^a, Vipul Jambukiya^b, Hemant Koshia^b^aK. B. Institute of Pharmaceutical Education and Research, Gandhinagar, Gujarat, India^bFood and Drugs Control Administration, First Floor, Block No. 8, Jivraj Mehta Bhavan, Gandhinagar, Gujarat, India**Abstract**

Food & Drug Control Administration (FDCA), can be credited with an iron hand and will of the regulator combined with the strict vigil and a friendly hand holding for all of its stake holders i.e., manufacturers of drugs, wholesalers, retailers, stockiest, C&F agents etc. The enforcement mission targets to fulfill the objective of making available the safe and effective medicines by ensuring that the menace of manufacture of spurious /substandard drugs is eradicated. For the enforcement activities it is vital to have immediate and accurate access to information as well as there is a need to communicate effectively and quickly with the stake holders. Prior to the initiative of implementation of software, SMS alerts etc. the enforcement task was dependent on manual means of actions and communications. Gujarat FDCA implemented web-based software - Xtended Licensing & Laboratory Node (XLN), <http://xlnfda.guj.nic.in/login.aspx>, with data stored in the central server. The aim behind e-governance was to create a system to bring about transparency, traceability, simplicity, effectiveness, harmonization, speed, accuracy and accountability in various G2G, G2C and G2B functions of the department and to attain & maintain FDCA's leadership in drug regulations in India.

Keywords: Food & Drug Control Administration (FDCA), Not of Standard Quality (NSQ), Xtended Licensing & Laboratory Node (XLN), Gujarat State Wide Area Network (GSWAN), Benefits to Business Community (G2B)

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1. Introduction

Food & Drug Control Administration (FDCA), Gujarat regulates the Sales & Manufacturing aspects related to Food, Drugs & Cosmetics. (1) FDCA head office is located in Gandhinagar and has 25 circle offices in various districts across the state. The jurisdiction of some of the circle offices is beyond one district. Each circle office is headed by an Asst. Commissioner and assisted by Drug Inspectors / Sr. Drug Inspectors for the field duties. Some of the key responsibilities of FDCA are:

Issuance of licenses: FDCA is the authority responsible for issuing licenses to stake holders for Manufacturing and Sales of pharmaceutical and related products i.e. manufacturers of drugs, wholesalers, retailers, stockiest, C&F agents etc. Licenses viz. Wholesale, Retail, Allopathic and Ayurvedic Product Permissions can now be applied through online system.

Enforcement: It includes monitoring of the quality of drugs manufactured or coming from other states. For the monitoring purpose each drugs inspector/Sr. Drugs Inspector has to draw drugs samples on regular basis. Drugs inspectors have to send these samples for analysis to the government drugs testing laboratory located at Vadodara, Gujarat. On the basis of test results samples declared as of Standard Quality or Not of Standard Quality. Moreover, based on the test results different types of punitive actions are entertained against the manufacturer. The enforcement mission targets to fulfill the objective of making available the safe and effective medicines by ensuring that the menace of manufacture of spurious /substandard drugs is eradicated. For the enforcement activities it is vital to have immediate and accurate access to information as well as there is a need to communicate effectively and quickly with the stake holders. Prior to the initiative of implementation of software, SMS alerts etc. the enforcement task was dependent on manual means of actions and

communications. The introduction of the new system has strengthened the enforcement function.

Laboratory Management: Ensure Collection of Samples to analysing them and lessen the time for the communication of the results with drug officers & conveying Sub Standard Drugs information to various stakeholder.

2. Challenges in the Enforcement

FDCA has been entrusted to ensure availability of quality medicines through licensed pharmacies and wholesalers by Health & Family Welfare Department of Government of Gujarat and thereby to promote & protect public health in the Gujarat state having population of more than 62 million.

The Sales licensing procedure is decentralized and prior to the initiative, it was carried out manually and lacked harmonization in all Circle Offices. Because of this some of the challenges needed to be taken care were identified:

Challenges in Multiple legal enrolments: Earlier pharmacists could illegally enroll their names in multiple pharmacies in different districts. During a drive conducted for verification of Pharmacists in pharmacies in the State, licenses of pharmacies with the absence of Pharmacists were cancelled by the FDCA.

Challenges in licensing procedure: The procedure for issue of sales license was tedious and time consuming. Right from the collection of application form to the issuance of the sales license, the applicant had to visit the circle office several times. The procedures in all circle offices were un-harmonized.

Disconnect because of distance: There was disengagement between the head office and circle offices. (i) The information related to sales licenses granted, suspended, cancelled, pharmacists etc. was not readily available with head office and hence effective monitoring of the working of the circle offices was difficult. (ii) The details of samples drawn by Drug Inspectors & Senior Drug Inspectors were not immediately available to Head Office. (iii) Difficulty in compilation and retrieval of information asked for by Parliament & citizens under the Right to Information (RTI) Act.

Procedural delays: The administrative procedure for “Not of Standard Quality” (NSQ) report was lengthy. After receipt of NSQ test report from laboratory, it took more than two months to convey the information to dealers, and by the time the NSQ information reached the dealers, most of stock was consumed and effective recall was not possible and the very objective of FDCA to protect public health was not being met.

No information access to public: No system for public to access the information related to pharmacies, NSQ drugs, Blood Banks, availability of blood etc.

Thus FDCA proposed a web based information technology solution to the problem which resulted into the current initiative – Xtended Licensing & Laboratory Node (XLN). (2)

3. Objectives of Xtended Licensing, Laboratory & Legal Node (XLN)

The initiative “XLN- Xtended Licensing & Laboratory Node” is a web based IT solution, <https://xln.gujarat.gov.in/>, with data stored in the central server. It evolved to the current features over a period of time XLN’s implementation which was initiated on 1st January 2007 with the following objectives:

- a) Standardization of procedures & bringing about transparency in administration.
- b) Effectively monitor the circle offices through this online IT application.
- c) Ensure that a pharmacist does not illegally enroll his name in multiple pharmacies in different districts - The software restricts him to one pharmacy only at a particular point of time.
- d) Reduce the number of personal visits to the circle offices by the applicant for expediting the decision on their application and to reduce their hardship.
- e) Details of samples drawn by Drug Inspectors & Senior Drug Inspectors and test reports needed be made available to Head Office immediately.
- f) Ensure quick & effective recall of NSQ medicines through mass messaging (SMS).
- g) Provide a seamless link between FDCA, Food & Drug Laboratory (FDL), Gujarat State Pharmacy Council and the Gujarat Medical Services Corporation Ltd. (GMSCL).
- h) To provide information in public domain, regarding medical stores / wholesalers and Blood Banks operating in Gujarat State.

4. Strategies for implementation of Initiative -XLN

Under the leadership and guidance of FDCA Commissioner, FDCA team & NIC Team discussed various aspects of the FDCA functions in several brainstorming sessions and worked out a plan for development of XLN- Xtended Licensing & Laboratory Node. (2)

- Several workshops were held with all Assistant Commissioners & Drugs Inspectors to demonstrate the software and to get their feedback.
- FDCA Commissioner ensured computer access in circle offices with the Gujarat State Wide Area Network (GSWAN) / internet connectivity. (3)
- FDCA team constantly monitored all circle offices to ensure that the details of 30,000 licenses in the software to generate database, and the sales licenses issued after 1st January 2007 were issued only through the software.
- FDCA team also constantly monitored all circle offices to ensure that details of each and every sample drawn by Drug Inspectors & Senior

Drug Inspectors are keyed in and necessary forms are generated through the software.

- NIC Team looked into the system requirements, its analysis, database designing, the development part & other technical aspects

5. Discussion

Stakeholders of XLN are: All circle offices of FDCA, FDCA's Head Office, Food & Drug Laboratory (FDL), Gujarat Medical Services Corporation Ltd. (earlier known as Central Medical Stores Organization - CMSO) (Government of Gujarat's central drug purchasing & distributing agency to all Government hospitals & dispensaries), Gujarat State Pharmacy Council (GSPC), Pharmacies (Retailers) and Wholesalers of drugs, Blood Banks and most importantly citizens.

5.1 Benefits to Government (G2G)

- XLN interlinks FDCA, DMLA, GMSCL, Drug laboratory and Pharmacy Council for co-ordination and monitoring. (2)
- Display of real time ranking of all Circle Offices on the basis of their performances.
- Real time statistical reports becoming available.
- Drug laboratory can immediately view the sample data entered by Drug Inspectors. No. of samples tested increased from 2409 to 6792 during 2005 to 2011.
- The test result entered by the laboratory can be immediately viewed by the concerned circle offices, Head office of FDCA and GMSCL.
- Drug Inspectors are alerted to initiate prompt action in various cases like:
 - a. 24 hours Pharmacy operating without 3 Registered Pharmacists.
 - b. Pharmacy operating without a mandatory Registered Pharmacist.
 - c. Firms "NOT INSPECTED" since last 1 year.
 - d. Firms whose Renewal is due in coming month.
 - e. Pharmacist at multiple locations within Gujarat.
- Administrative uniformity, accuracy, speed, transparency and instant accessibility of information through XLN helped to increase performances of circle offices. (2) During year 2005 to 2011, number of disposal of applications increased to 10827.
- As XLN is replicated by other seven states, access to their databases on – drug inspectors, sales licensee etc.
- Maintains the history of all data.

5.2. Benefits to citizen (G2C)

- Citizen can locate nearby Pharmacies.
- Information about 24 Hours functional Pharmacy is available.
- Information about all NSQ Drug Samples.
- FDCA offers free testing of food to the citizens through its mobile testing van.
- Information about upcoming Blood Donation Camps, availability of Blood Bags of each Blood Group and Blood Component with the Blood Banks
- Plan to start Patient Information Leaflet in Gujarati language on portal.
- Academic institute students can support role for more awareness about medicine use, storage, Adverse drug reaction reporting, Generic medicines, Patient counselling etc.

5.3. Benefits to Business Community (G2B)

- **Status of an application** with reasons can be accessed.
- XLN compels the Drugs Inspector and Assistant Commissioner (Licensing Authority) to follow FIFO (First in, First Out) system after lapse of predetermined time limit for each stage and prevent "Red Tapism". During year 2006 to 2011, no. of days to expedite various applications reduced drastically - fresh License from 36 to 15 days, renewal of licenses from 180 to 30 days and other applications 60 to 40 days.
- Wholesalers can get information of any Pharmacy.
- Availability of registered Pharmacists in any particular area can be accessed.
- SMS alerts sent to all pharmacies & Wholesalers for drug samples declared as "Not of Standard Quality" (NSQ) by Drug Laboratory which helps them to stop sale / distribution and recall from the market. This is the first ever initiative taken by any Drug Controller to ensure effective recall of NSQ medicines and thereby protecting public health. SMS is also sent to other State Drug Controllers and select media personals.

5.4. Note on the cost effectiveness of the project

Gujarat State Wide Area Network (GSWAN) across the state already existed. (3) Therefore, no extra cost for establishing a cloud server and networking was required. Internet connectivity obtained through special permission from Government of Gujarat for few district offices where GSWAN connectivity was not available. National Informatics Centre, Gujarat's Team's technical expertise for system requirements, its analysis, database designing, the development part & other technical aspects were utilized. Central Server hosting, mirroring of data and regular backups was carried by NIC. The

funds were provided by the Government of Gujarat. Thus, the project was implemented in very cost effective way.

5.5. Impacts of XLN initiative

XLN has enhanced trust, confidence and image of FDCA for better regulation and public services among all stakeholders including citizens. XLN has played major role in ensuring efficiency and curbing corruption in FDCA, Gujarat. XLN received appreciation for better public services at several conclaves and published in various print media. "To make public Services transparent and efficient", Government of Gujarat rewards its various departments for their exemplary initiatives. During March 2012, Dr. H.G. Koshia Commissioner, FDCA, Gujarat was awarded the first award under above category for the FDCA, Gujarat's initiative of XLN. XLN initiative received "CSI IT Excellence Runner up award" from the Computer Society of India, a premier computer society association operating since more than 50 years in India. Government of India conferred "National e-Governance Gold Award 2012-2013 for Exemplary Re-Use of ICT based solution" on FDCA and Dr. H.G. Koshia, Commissioner, FDCA for XLN initiative. XLN received an e-India Award 2013 & Certificate of Excellence for Government initiative in Healthcare. Thus, XLN has further strengthened the position of FDCA, Gujarat as leading State Drug department in the country.

Table 1. Good Regulatory Practices by XLN database (2)

Year	2005	2011	2022
Sample tested	2,409	6,792	10,484
Disposal	6,103	10,827	18,528
Manufacturers	3,631	3,530	5,744
Retailers	10,598	13,349	27,818
Wholesalers	10,370	13,062	22,933
Blood Banks	83	111	180

6. Conclusion

The massive database of the stakeholders build by the Gujarat FDCA has plays a very important role in achieving 100 per cent effectiveness of XLN. Successful implementation of XLN by FDCA, Gujarat and followed by other States has been noted by DeitY, Govt. Of India and DeitY, Govt. Of India has identified XLN as a RAPID ROLLOUT & REPLICATION Project- Replicated in seven States with one Application LOGIN & one Database. XLN has been recommended by DCGI to all States and it shall be implemented all States to bring transparency, speed, accuracy, sharing of vital information and harmonization in implementation of the Drugs & Cosmetics Act and Rules.

Thus, XLN has helped to bring stronger networking, regular and faster alert system, feedback, harmonization, speed, accuracy, effectiveness, accountability and transparency in functions related to G2G, G2C and G2B and to attain & maintain FDCA's leadership in drug regulations in India.

Future initiatives viz. Patient Information Leaflets in Gujarati language to be made available online for the

citizens for all the drugs available in the market and many more to come as Gujarat FDCA works round the clock for the up-liftman of their end users.

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Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article

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