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Review Article

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Drugs Manufacturing License Allocation (DMLA): An Effective Tool for e-Governance in fields of Drugs Manufacturing Regulation

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Abstract

Gujarat's Food & Drug Control Agency (FDCA) oversees the manufacturing and sales of food, drugs, and cosmetics. The FDCA is the organisation in charge of giving licences to parties involved in the production and sale of pharmaceuticals and related goods, such as drug makers, wholesalers, retailers, stockists, C&F agents, etc. The enforcement mission is to achieve the goal of making safe and effective medications available by ensuring that the menace of the production of fake/substandard drugs is eliminated. Access to information that is current and accurate, as well as the ability to speak with stakeholders clearly and promptly, are essential for enforcement actions. The enforcement task was dependent on manual methods before the initiative to incorporate software, SMS notifications, etc. The initiative "DMLA- Drugs Manufacturing License Allocation" is a web based IT solution, http://dmla.guj.nic.in/mfg/myaccount/Home.aspx, with data stored in the central server. The introduction of the new system has strengthened the enforcement function. It has helped to achieve and maintain FDCA's leadership in drug regulation in India by bringing consistency, speed, accuracy, effectiveness, accountability, and transparency to G2G, G2C, and G2B operations.

Keywords: Gujarat's Food & Drug Control Agency (FDCA), DMLA- Drugs Manufacturing License Allocation, iDMLA portal, DCGI

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1. Introduction

Food & Drug Control Administration (FDCA), Gujarat regulates the Sales & Manufacturing aspects related to Food, Drugs & Cosmetics. (1) Food & Drugs Control Administration, (FDCA) Gujarat State is regulatory authority for enforcement of Drugs & Cosmetics Act -1940 and Rules 1945 in the state of Gujarat. It includes licensing of various drugs manufacturing in the Gujarat State.

Activities to issue and control the Drugs (Allopathic) licenses are carried out by office of Commissioner, Food & Drugs Control Administration (FDCA), Gandhinagar. There are 25 circle offices working under the FDCA at district level which enforce the Drugs & Cosmetics Act -1940 and Rules 1945 in the state of Gujarat.

The web enabled software is rolled out across the state and operational in all 25 circle offices catering services to 33 districts of Gujarat.

Two web portal is developed to cater the service related to Drugs (allopathic) Manufacturing Licenses.

DMLA (Drugs Manufacturing License Allocation for FDCA office users). (2)

iDMLA (Drugs Manufacturing License Allocation for manufacturers). (3)

All Technical Officers and concerned ministerial staff of FDCA have access to the software through DMLA portal.

More than 1200 drugs (allopathic) manufacturing companies are given a login credentials to access the iDMLA portal which is accessible over the internet from anywhere of the world with no geographical restrictions. The drug manufacturing company may have multiple manufacturing sites and licenses to manufacture drugs. They can maintain their profile through this portal for such multiple units / licenses. Till date more than 4300 manufacturing Licenses and more than 234800 Product licenses are being managed through DMLA/iDMLA. Gujarat State is the hub of Pharmaceutical manufacturing and almost 33 % of total pharmaceuticals manufactured in India are manufactured in Gujarat State.

Food & Drugs Control Administration, (FDCA) Gujarat State is regulatory authority for enforcement of Drugs & Cosmetics Act -1940 and Rules 1945 in the state of Gujarat and includes licensing of various drugs manufacturing in the Gujarat State. Commissioner, FDCA is the State Licensing Authority to grant / renew licenses, product licenses, approval of technical persons etc. All such applications are being processed by H.Q., Gandhinagar.

Considering the quantum of work with FDCA, Commissioner, FDCA has also delegated various powers to FDCA's senior officers like Joint Commissioners, Deputy Commissioners and Assistant Commissioner at H.Q., Gandhinagar.

Manual Processing of the applications & lack of tracking system was the common difficulty same as with any other Government department. The data regarding Licenses, Constitution of the firm, technical Persons, Product Licenses were maintained as physical files only.

Also, the complexity and variety of product licensing types were the specific issues with the numerous product licences issued by FDCA. As on date, 4317 Drug manufacturing Licenses are operational in Gujarat State. As on date, 230,760 product licenses have been granted by FDCA.

All these data vary in many aspects and are too complex:

- A manufacturer may have more than one unit in Gujarat State.
- A manufacturer may also have Loan Licenses with multiple parent firms.
- A manufacturer may have product licenses in the range of 10 to 1500.
- One product License may have ingredient in the range of 1 to 30.
- One Product may be in various dosage forms e.g. Tablet, Capsule, Oral Liquid, Small Volume Parenteral, Large Volume Parenteral, Metered Dose Inhalers, Ointment, Cream, Lotion, Nasal drop/spray etc.
- A product may be of different categories like Bulk Drug, Formulations, Irrigating solutions, Vaccines, r-DNA products, Blood & Blood Products, Diagnostic Reagents, Sutures, Mechanical Contraceptives like – condom, Copper –T etc. Medical Devices – Cardiac Stents, Orthopaedic Implants, IOL (Intra Ocular Lenses), IV Sets, Needles, Syringes etc.
- Every day approx. 150 new product licenses are being processed by FDCA, Gujarat.
- Queries raised by the FDCA officers took several days for manual communication to the applicants and thereby the compliance by the applicant also took another several days. Ultimately, there was delay in granting product licenses.

To track a product license with a particular ingredient / composition was a time consuming task.

Whenever DCGI, Government of India ban a particular API (Bulk Drug) / composition of a formulation, practically, it was not possible to retrieve the information correctly and completely in the given time while it is necessary to ask the manufacturers to stop manufacturing of such banned drugs. RTI applicants ask information of a manufacturer manufacturing a particular drug / formulation, information retrieval was likewise impractical in such a setting.

During submission of License renewal application, a manufacturer may or may not include all Product Licenses granted earlier as per their requirement. The list of Product Licenses submitted with the renewal application need to be compared along with the copies of original Product Licenses. The manual process of such application is a tedious & time consuming task.

The manufacturer located at the distance places like Bhuj / Vapi etc. had to travel at least 400 km to reach FDCA Head Quarter at Gandhinagar to apply and know the status of the applications and had to make overnight stays for several days at Gandhinagar. Moreover, they may have to return to their working place / company for the compliance of the queries. The entire process was costing not only considerable amount of money but also wastage of important working man-hours'.

In case of epidemic & pandemic situation / short supply of a particular medicine, information of a manufacture manufacturing such medicine was not availed within time frame.

Annual Surveys of the drug manufactured, capital investments etc. by all manufacturers located in Gujarat State and compilation of all these information took several months and frequently couldn't finish till the end of the year.

Conventional method of sending circulars through post to pass on particular information to all manufacturers and even to FDCA officers was not prompt, effective and was expensive.

2. Extent of Process re-engineered

The complexity of application & grant of product license was simplified and standardized through online application through iDMLA & DMLA.

During submission of License renewal application, the comparison between the submitted and already approved original product licences was simplified and made more convenient by permitting the applicant firm to select already approved & verified product licenses from the database.

Annual survey – return filing was made online and the manufacturer can enter the details directly through iDMLA and the information of all manufacturers gets compiled automatically. This enabled FDCA to complete the survey on time and actual data became available.

The numbers of various types of application submitted by the applicant drug manufacturers, processed and

disposed can be accessed for any specific period as reports. MIS, annual and specific period reports can be easily generated.

3. Strategy Adopted

Gujarat State is the hub of Pharmaceutical manufacturing and almost 33 % of total pharmaceuticals manufactured in India is manufactured in Gujarat State.

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Considering the quantum of work with FDCA, Commissioner, FDCA has also delegated various powers to FDCA's senior officers like Joint Commissioners, Deputy Commissioners and Assistant Commissioner at H.Q., Gandhinagar.

A workflow based application of Drugs (allopathic) Manufacturing License is developed for Food & Drugs Control Administration (FDCA), Health Department, Govt. of Gujarat.

National Informatics Centre, Gujarat State has been entrusted the task to develop the software. Several brain storming sessions between FDCA & NIC team took place before, during & after development of the software.

Two web portals are developed under this project. One portal called iDMLA is a web portal accessible over internet for the drugs (allopathic) manufacturers and another called DMLA is for FDCA. The online application submitted in iDMLA by applicant is automatically reflected in DMLA (portal for FDCA officers) once registration process is completed.

DMLA *(2)*

This is a workflow based application processing and having role based access. The scope of the project is Firm Registration Management, Firm Profile verification and updating, issuance of fresh license, renewal and amendments in existing license, additional product license, Revised Product License, Additional Brands and various types of certificates.

iDMLA *(3)*

This is a portal for drugs (allopathic) manufacturer where they are registering themselves. After the verification of genuineness of the firm by FDCA, firm is able to login into the portal by providing credentials they have given at the time of registration.

Manufacturer can manage their license & product profile. They can do various on-line applications like Fresh License, Renewal of License, Amendments in License, surrender of license / product license, additional product licenses, application for certificates, approval of Technical Persons etc.

- Web based application accessible over intranet/internet
- Complete workflow based application processing
- Role based access
- Drugs (manufacturer) registration on iDMLA portal. The basic details of Firm Profile are also available to the Drug's manufacturer
- Registering through on-line application on portal.
- On-line application status
- News and other alert in the form of E-message to the registered manufacturers (allopathic drugs)
- Intimation of notice to the manufacturer on the portal.
- Alerts to the license holder about the validity of license
- SMS alert on disposal of application

4. Activities Covered

a) Firm Registration and Verification: Assigning of user credentials to the firm after verifying the genuineness of the firm

b) Managing Firm Profile: This covers License, Technical Persons, Product Licenses, and Certificates etc.

c) On line submission of Various applications and workflow based processing of an applications. Like…

- Additional Product Licenses
- Renewal of Licenses
- Surrender of Licenses/Product License
- Amendments in License
- Application for Technical Person approval
- Application to avail various certificates

d) Annual Return filing

e) News and messaging system

f) SMS alerts

g) License and Product Licenses Management.

To full fill the above requirements a detailed study was conducted and area for computerization was identified.

The biggest issue with the manual system was the lack of accurate record-keeping for Pharma manufacturers and the medications they produced. Also they have to visit N number of times to the office to get the work done.

The major challenge found during the study were

- To assign the user credentials to all drugs manufacturing firms(allopathic)
- To enter the all legacy data like drugs manufacturing license and products licenses

(Approx. 150000 product licenses) granted to them. To enter the existing product license details with its composition details was in itself a huge task.

- Online submission and processing of various applications

To overcome from above problems the whole project was divided into 3 phases.

4.1 Phase-1 The Firm Registration

In this phase all drugs manufactures were asked to register themselves on iDMLA portal and submit the registration slip to the FDCA office with necessary supporting documents to prove the genuineness of the firm.

After verifying the genuineness of the firm by the FDCA officials, the user credentials of the firm, provided by themselves at the time of registration, gets enabled automatically. Then onwards firm can login into the iDMLA portal- a portal of drugs manufacturers.

4.2 Phase-II Firm Profile Update

During this, manufacturing firms have been asked to update their profile. This includes the existing details of

- Details of the licenses they have
- Approved Product Sections
- Approved products (drugs) with compositions
- Technical Persons they have engaged in manufacturing process.

The above details entered by the firm must get verified by the FDCA office. After verification of the profile, the firm is entitled to submit various applications online through iDMLA portal.

4.3 Phase-III Online applications.

Once the firm profile is verified, the manufacturer is now free to lounge various application on iDMLA portal.

Thus, project was rolled out across the state by above phase wise. The most complex part of the entire licensing activities like product licenses was focused first. To achieve this, number of interactive workshops in almost all major districts had been arranged with manufactures to train them. These workshops proved beneficial for FDCA, NIC & the applicants. Their valuable feedbacks were also taken into considerations.

5. Technology Platform used

- Web based application developed in ASP.NET and SQL Server 2008 as a backend. SQL server reporting service has been used.
- Hosted on NIC Data centre and accessible over internet
- Windows 8 server with IIS
- 3 tier application architecture
- Single Sign On – User authentication.
- Role base access of the menu
- Audit trial
- No Service Level Agreement Carried out. Permanent technical support by NIC

6. User convenience

(i) Service delivery channels (Web, email, SMS etc.)

The portal iDMLA is specially launched for the applicant manufacturers whereby they can enter & update their profile, licenses details, technical persons details, product licenses, online applications etc. The applicant manufactures are intimated the status of the online application like query, approval or cancel/reject through SMS on the mobile number registered by the applicant firm.

(ii) Completeness of information provided to the users,

The applicant can access complete profile of the firm and all their licenses.

The applicant can also access the approved product Licenses through iDMLA.

(iii) Accessibility (Time Window),

The iDMLA portal is available to the applicant 24X7, anytime, anywhere.

(iv) Distance required to travel to Access Points

The applicant has access to the iDMLA through desktops / laptops and even through smart phones. No travelling required.

(v) Facility for online/offline download and online submission of forms,

The applicant requires submitting online application. The approved product licenses and other information can be retrieved as .pdf file and it can be downloaded and saved.

(vi) Status tracking

The advantage of this project is “Status tracking” of any online application.

The applicant manufactures are intimated the statuses of the online application like query, approval or cancel/reject through SMS on the mobile number registered by the applicant firm.

Applicant can also read the query raised by FDCA officer as the tool tip added to the application number of the iDMLA.

7. Capacity Building and Organizational Sustainability

DMLA – iDMLA project is the result of combination of vast experience of FDCA officers and National Informatics Centre, Gujarat’s Team’s technical expertise. FDCA officers have contributed their expertise in the legal & technical matter and NIC officers have contributed their IT expertise like system requirements, its analysis, database designing, the development part & other technical supports like Central

Server hosting, mirroring of data and regular backups. Thus, the entire project may be considered as in house project of Govt. of Gujarat & Govt. of India.

FDCA officers working at district offices and the manufacturers of each district were called for interactive trainings for iDMLA & DMLA. The workshops were not limited to impart training only but to seek their suggestions & feedbacks to improve the project.

The project conceptualization was started in 2008. Firm's registration, data entry for the firm, verification and freezing of data by FDCA officers was a huge task requiring lot of man-hours'. More than 1,50,000 back log entries of product licenses were keyed in, verified and freezed. Trials of online product licenses processing and standardization as pilot project completed and then after online renewal applications were started on date 23rd January 2013. Thus, before commencement of the project adequate checks were made to ensure that the project performs as per the requirements. More than 80000 online applications have been successfully processed. It proves the robustness of the software.

8. Accountability and Appropriate Delegation

iDMLA - The applicant firm has been permitted to generate user ID and password for two persons – operator and manager. They have been assigned various level of authority for submitting online application / updating profile.

DMLA – User ID & Password has been allocated to clerical staff, Drugs Inspectors, Senior Drugs Inspectors, Assistant Commissioners, Deputy Commissioners, Joint Commissioners and Commissioner of FDCA. Depending upon the job authority & responsibility, each person has been given access & authority to certain level of processing the online application and view reports as well.

iDMLA & DMLA portal has distinctive features of appropriate "Power delegation" for employee of the applicant firm and each clerk / officer of FDCA depending upon their assigned job profile.

Log book of each activity performed in iDMLA & DMLA is being maintained by NIC for tracing & fixing responsibility.

9. Results and Discussion

(i) Benefits to Government (G2G)

a) Generation of huge & verified electronic data of more than 4300 Licenses & 234800 product Licenses. FDCA, Gujarat is the first and only State Licensing Authority to have database.
b) Ease of retrieval of various types of information for technical matter or RTI application.
c) Prompt action, when any ingredient / composition banned by DCGI, New Delhi.
d) Prompt communication of queries through SMS / online status. Prompt compliance by the applicant lead to quicker expedition of the application.
e) Prompt and correct collection and compilation of information, like drugs manufactured in Gujarat State.
f) Better & prompt mass communication with all manufacturers and FDCA officers. Better execution.
g) Indian Drug Manufacturer's Association (IDMA) has appreciated the project in writing.
h) This project has simplified the product licensing processing and thereby saving the time consumption of FDCA officers. The time saved by this project can be productively utilized by FDCA officers in other enforcement activities.

(ii) Benefits to citizen (G2C)

a) Prompt retrieval of information manufacturing a particular drug helps FDCA to act promptly (e.g. Drugs banned by DCGI, New Delhi) and thereby protecting public health.
b) In case of epidemic & pandemic situation / short supply of a particular medicine, information of a manufacture manufacturing such medicine can be availed with just few clicks with the help of this software and thereby FDCA can direct such manufacturers to carter the demand and protect public health.

(iii) Benefits to other stakeholders (G2B)

a) A firm / company may be having several licenses for one or more than one manufacturing units &/or loan licenses. They can access the information of each licenses 24X7 from any corner of Globe.
b) The firm has access to detailed information of any product license and can download as .pdf file and also send it to the buyer in response to business inquiry or even for registration in other countries. Helps to boost business and export too.
c) Effective tracking of online application and prompt intimation of grant of product licenses through SMS reduces gestation time for launching a particular product in market.
d) The manufacturer located at the distance places like Bhuj / Vapi etc. had to travel at least 400 km to reach FDCA Head Quarter at Gandhinagar to apply and know the status of the applications and had to make overnight stays for several days at Gandhinagar. Moreover, he may have to return to their working place / company for the compliance of the queries. The entire process was costing not only considerable amount of money but also wastage of important working man-hours'.

10. Note on the cost effectiveness of the project

Gujarat State Wide Area Network (GSWAN) across the state already existed. (4) 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. Optimum usage of limited computers and printers

available with FDCA was ensured. 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.

11. Conclusion

The Successful implementation of DMLA by FDCA done in Gujarat to bring transparency, speed, accuracy sharing of vital information and harmonization in implementation of the Drugs & Cosmetics Act and Rules.

Thus, DMLA has helped to bring 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.

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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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