



SUGAM

**National online portal for
Manufacturing and Sales
(Proposed)**

Purpose/ Objective of National Online Port

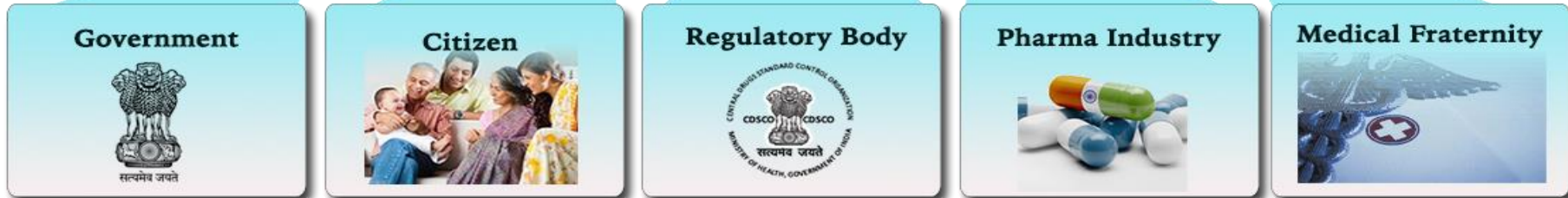


- Establish Single window Platform for application for manufacturing license.
- Establish Single window Platform for sales and Distribution License.
- Establish Single window Platform for COPP/WHO GMP Application.
- Establish Uniformity w.r.t the requirement of documents for different type of applications throughout India.
- Greater outreach of citizen centric information
- Ease for Stakeholders
- Accountability, transparency, Reliability and timely process of the applications
- Real time trending of application

Stakeholders



SUGAM



Governance & International visibility

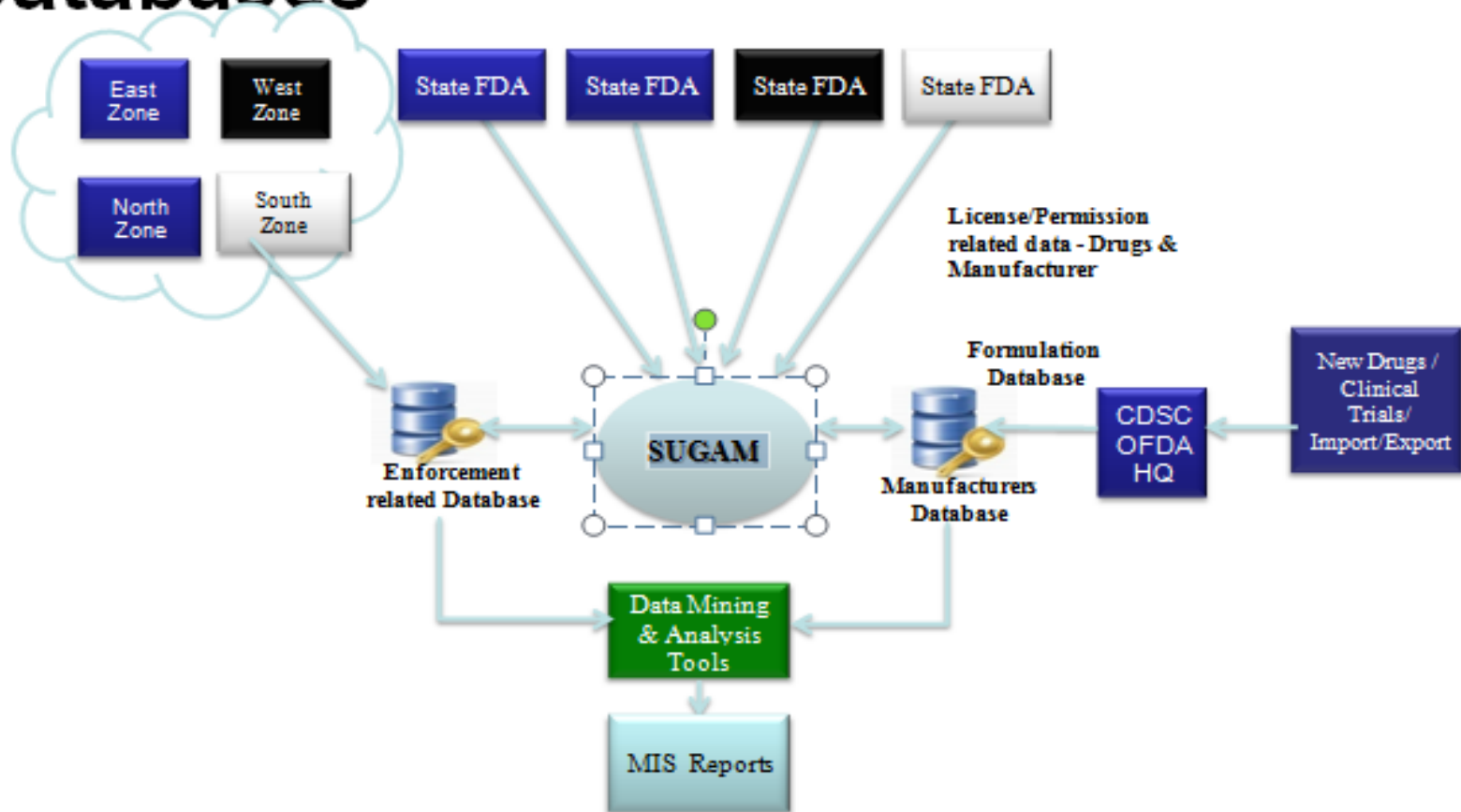
Citizen Centric Real Time Information

Better Control, Monitoring & Streamlined processes

Promotes Indian pharmaceutical Industry growth

New Drugs Information

Integrated Databases



Requirement of National Portal for Regulatory applications

- The proposed National portal proposal was discussed in Drugs Consultative Committee (DCC) meeting.

The proposed Model design is based primarily on type of applications defined under Drugs and Cosmetics Rules and supportive documents to be uploaded in the checklist.

Experiences and inputs from Gujarat, Maharashtra and M.P. And other states have been taken for developing this state portal

Steps involved in Portal

Registration (Corporate/Company etc.)



Registration of Manufacturing sites and sale premises



Submission of application as per the required application forms

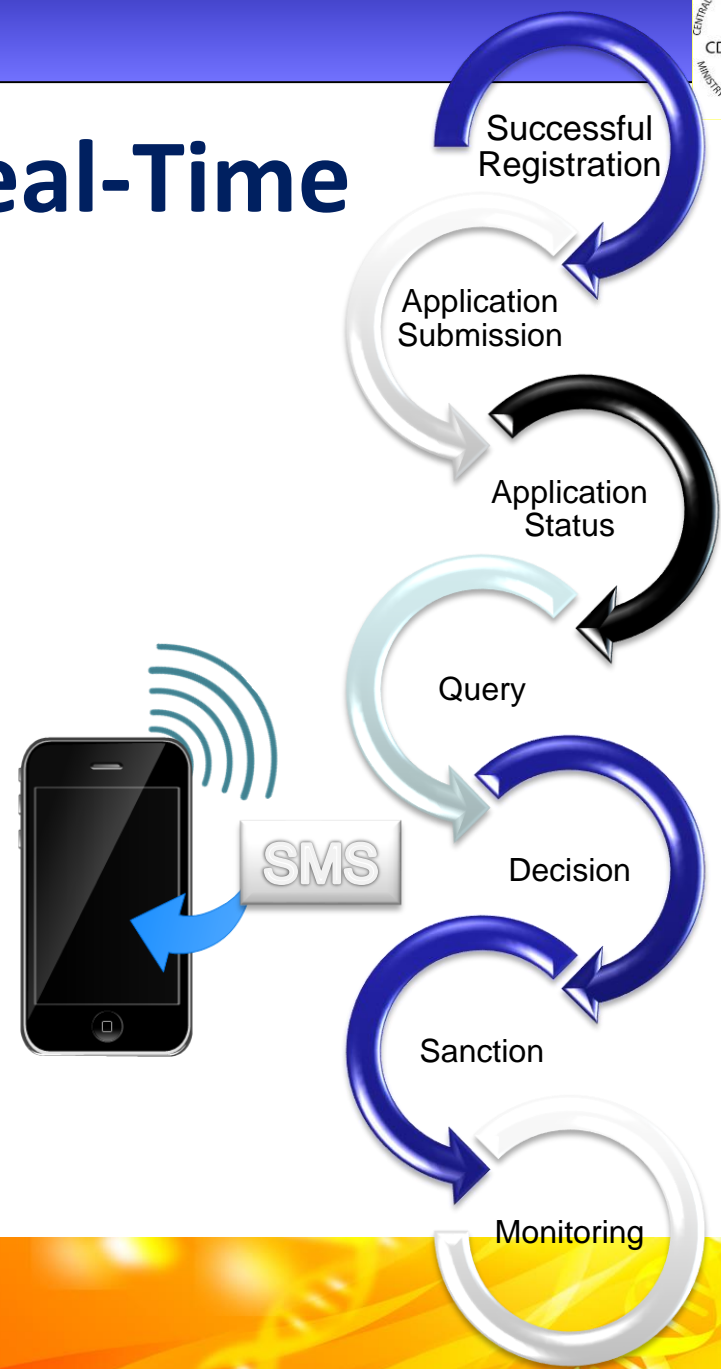


Processing of applications depending on the type of application.



Issuance of Licenses/Certificates

Online Submission & Real-Time Tracking of Application



Types of applications

Manufacturing

- Manufacturing Licenses
- CoPP
- WHO/GMP Certificate
- Blood Bank and Blood products

Sales

- Retail/Wholesale

Forms and Licenses to be applied in Portal for Manufacturing (SLA items)

Appl Form	Title	Lic Form	Title
24	Application for the grant of or renewal of a licence to manufacture for sale or for distribution of drugs other than those specified in [Schedule C, C (1) and X]	25	Licence to manufacture for sale or for distribution of drugs other than those specified in 2 [Schedules C and C(1) and X]
24A	Application for grant or renewal of a loan licence to manufacture for sale or for distribution of drugs other than those specified in Schedule C, C (1) and X	25A	Loan licence to manufacture for sale or for distribution of drugs other than those specified In 2 [Schedules C and C (1) and X]
24B	Application for grant or renewal of a licence to repack for sale or distribution of drugs, being drugs other than those specified in Schedule C and C (1) excluding those specified in Schedule X	25B	Licence to repack for sale or distribution of drugs being drugs other than those specified in Schedules C and C (1) excluding those specified in Schedule X
24C	Application for the grant or renewal of a licence to manufacture for sale or for distribution of Homoeopathic medicines or a licence to manufacture potentised preparations from back potencies by licensees holding licence in Form 20-C	25C	Licence to manufacture for sale or for distribution of Homoeopathic medicines
24D	Application for the grant / renewal of a licence to manufacture for sale of Ayurvedic/ Siddha or Unani drugs	25D	Licence to manufacture for sale of Ayurvedic (including Siddha) or Unani drugs
24E	Application for grant or renewal of a loan licence to manufacture for sale Ayurvedic (including Siddha) or Unani Drugs	25E	Loan Licence to manufacture for sale Ayurvedic (including Siddha) or Unani Drugs
24F	Application for grant or renewal of a licence to manufacture for sale or for distribution of drugs specified in Schedule X and not specified in Schedule C and C(1).	25F	Licence to manufacture for sale or for distribution of drugs specified in Schedule X and not specified in Schedules C and C(I)

Appl Form	Title	Lic Form	Title
27	Application for grant or renewal of a licence to manufacture for sale or for distribution of drugs specified in Schedule C and C (1) excluding those specified in part XB and Schedule X	28	Licence to manufacture for sale or for distribution of] drugs specified in Schedules C and C (1) 2 [excluding those specified in Schedule X
27A	Application for grant or renewal of a loan licence to manufacture for sale or for distribution of drugs specified in Schedule C and C (1) excluding those specified in part XB and Schedule X	28A	Loan Licence to manufacture for sale or for distribution of] drugs specified in Schedules C and C (1) excluding those specified in Schedule X
27B	Application for grant or renewal of a licence to manufacture for sale or for distribution of drugs specified in Schedules C, C (1) and X.	28B	Licence to manufacture for sale or for distribution of drugs specified in Schedules C, C(I) and X

Appl Form	Title	Lic Form	Title
30	Application for grant or renewal of licence for purposes of examination, test or analysis.	29	Licence to manufacture drugs for purposes of examination, test or analysis
31	Application for grant or renewal of a licence to manufacture cosmetics for sale or for distribution	32	Licence to manufacture cosmetics for sale or for distribution
31A	Application for grant or renewal of a loan licence to manufacture cosmetics for sale [or for distribution]	32A	Loan licence to manufacture cosmetics for sale or for distribution
47	Application for grant or renewal of approval for carrying out tests on Ayurvedic, Siddha and Unani drugs or raw materials used in the manufacture thereof on behalf of licensees for manufacture for sale of Ayurvedic, Siddha and Unani drugs	48	Approval for carrying out tests or analysis on Ayurvedic, Siddha and Unani drugs or raw materials used in the manufacture thereof on behalf of licensees for manufacture for sale of Ayurvedic, Siddha and Unani drugs
36	Application for grant or renewal of approval for carrying out tests drugs/cosmetics or raw materials used in the manufacture thereof on behalf of licensees for manufacture for sale of drugs/ cosmetics.	37 (Sch C & C1)	Approval for carrying out tests on drugs / cosmetics and raw materials used in their manufacture on behalf of licensees for manufacture for sale of drugs /cosmetics

Forms and Licenses to be applied in Portal for Manufacturing (CLAA items)

Appl Form	Title	Lic Form	Title
27C	Application for grant/renewal of licence for the operation of a Blood Bank for processing of whole blood and / or preparation of blood components.	28C	Licence to operate a Blood Bank for collection, storage and processing of whole human blood and/or its components for sale or distribution
27E	Application for grant /renewal* of licence to manufacture Blood products for sale or distribution	28E	Licence to manufacture and store blood products for sale or distribution.
27F	Application for grant or renewal of licence Collect, Process, Test, Store, Banking And Release Of Umbilical Cord Blood Stem Cells.	28F	Licence To Collect, Process, Test, Store, Banking And Release Of Umbilical Cord Blood Stem Cells.
27D	Application for grant or renewal of a licence to manufacture for sale or for distribution of Large Volume Parenterals/Sera and Vaccines excluding those specified in Schedule X	28D	Licence to manufacture for sale or for distribution of Large Volume Parenterals/Sera and Vaccines/recombinant DNA (r-DNA) derived drugs specified in Schedules C and C(I) excluding those specified in Schedule X

Forms and Licenses to be applied in Portal for Manufacturing (CLAA item)



Appl Form	Title	Lic Form	Title
27DA	Application for grant or renewal of a loan licence to manufacture for sale or for distribution of large volume parenterals/sera and vaccine/recombinant DNA (R-DNA) derived drugs excluding those specified under Schedule X	28DA	Loan licence to manufacture for sale or for distribution of Large Volume Parenterals/Sera and Vaccines/recombinant DNA (r-DNA) derived drugs excluding those specified in Schedule X

Forms and Licenses to be applied in Portal for Sales and Distribution

Application Form	License Form	License Type
19	20	Retail
	21	Retail
	20B	Wholesale
	21B	Wholesale
19B	20C	Retail- Homeopathic
	20D	Wholesale- Homeopathic
19C	20F	Retail – Sch. X Drug
	20G	Wholesale – Sch. X Drug
19A	20A	Retail – Restricted
	21A	Retail – Restricted
19AA	20BB	Vehicle
	21BB	Vehicle

Other Online services

- **Change in constitution**
- **Change in premises**
- **Additional License.**
- **License renewal**
- **Change in pharmacist/Change in competent person**
- **Change in Name**
- **Addition or Reduction in premises**
- **Change in specific condition**
- **Surrender of License**
- **Duplicate License**
- **Change in Director**
- **No conviction certificate**
- **Free sale certificate**

Thank you