

CHAPTER 13

Good Regulatory Practices

13.1. GOOD REGULATORY PRACTICES (GRP) IN COMMUNITY AND HOSPITAL PHARMACY

13.1.1. Introduction

Good Regulatory Practices (GRP) is processes, systems, tools, and methods for improving the quality of regulations that are internationally recognised.

Before government initiatives are implemented, GRP systematically implements public consultation and stakeholder involvement, as well as impact analysis of government proposals to ensure they are fit for purpose and will achieve the goals set out.

13.1.2. Principles of Good Regulatory Practices

Table 13.1: Principles of Good Regulatory Practice

Legality	Regulatory systems and the choices that result from them should be formed legally.
Consistency	Regulatory control of medical products should be reliable with existing government policies and legislation, and should be administered in a predictable and consistent manner.
Independence	Institutions should have independent regulatory control of medical product.
Impartiality	All regulated parties should be handled equally, fairly, and without bias.
Proportionality	Regulation and regulatory choices should be proportional to the risk and the ability of the regulator to implement and enforce them.
Flexibility	Regulatory control should not be prescriptive, instead should allow flexibility in responding to changing conditions and unexpected events. The regulatory system should include provisions for quick response to public health emergencies.
Clarity	Users should be able to access and understand regulatory requirements.
Efficiency	Regulatory systems should fulfil their objectives in the required time and at a reasonable cost and effort. International collaboration increases efficiency by allowing for the most efficient use of resources.
Transparency	Transparency in regulatory systems is essential; requirements and choices should be made public and public feedback on regulatory proposals should be asked.

13.2.1. Documentation

The following documents are the pre-requisites for the application of Drug Sales License.

- 1) Affidavit attested by Public Notary:
 - i) Of Proprietor, if the applicant firm is proprietorship firm
 - ii) Of all the partners, in case the firm is a partnership firm
 - iii) Of the person duly authorised by the Board of Directors of the Private Limited or Limited Company
- 2) Copy of partnership deed if partnership firm
- 3) Address proof of the authorised proprietor / applicant (copy of voter I.D., driving license)
- 4) Affidavit of the liable person for day-to-day working and for any violation of laws pertaining to Drugs.
- 5) Documents related to Pharmacist:
 - i) Affidavit duly attested by Public Notary
 - ii) Copies of educational qualification certificates (Attested)
 - iii) Attested copy of registration certificate and its renewal issued by U.P. Pharmacy Council.
 - iv) Two photographs per applied license
 - v) Address proof
 - vi) Appointment letter and joining letter
- 6) Documents related to qualified person (for Wholesale license):
 - i) Attested copies of educational qualification certificates
 - ii) Experience certificate on the affidavit
 - iii) Two photographs per applied license
 - iv) Appointment letter and Joining letter if applicable
 - v) Three copies of the plan of proposed premises
- 7) Documentary proof of rental or ownership basis of the proposed premises
 - i) Photocopy of the rental agreement in case of rented premises
 - ii) Attested copy of ownership proof of rented premises from the landlord
- 8) Two photographs of Proprietor/Partners/Authorised person
- 9) Attested copy of purchase invoice of a refrigerator

13.2.2. Licenses

While applying offline, the fees should be paid in the Government Treasury or Government Branch of State Bank of India of the district where the license is required. The original of the treasury challan must be submitted with the application.

Type of Sales License	Fees for Grant of License
For Wholesale license	Rs. 1500+1500= Rs. 3000.00
For Retail License	Rs. 1500+1500= Rs. 3000.00
For Restricted License	Rs. 500+500= Rs. 1000.00
For Drugs specified in Schedule-X (Wholesale)	Rs. 500
For Drugs specified in Schedule-X (Retail)	Rs. 500

13.2.3. Renewals

Renewal of Sale license should be made on the application form same as the form submitted during the grant of the new license along with the necessary fee. The Fee for the renewal of the license is same as the grant of license. The late fee for the renewal of the license is as follows that is applicable up to six months.

Late fee for Renewal

Per month

Rs. 500+500 = Rs. 1000.00

Rs. 500+500 = Rs. 1000.00

Rs. 250+250 = Rs 500..00

Rs. 250.00

Rs. 250.00

Documents Required for Renewal

- 1) Copy of last renewal
- 2) Affidavit of Pharmacist and current rent agreement
- 3) Address proof of the authorised proprietor/applicant
- 4) Affidavit of the liable person for day-to-day working and for any violation of drug laws

13.3. GRP IN PHARMA MANUFACTURING

13.3.1. Documentation

The following documents are the pre-requisites for the application of Drug Manufacture License:

- 1) Affidavit of the following attested by Public Notary:-
 - i) Proprietor of the applicant firm, in case the firm is proprietorship firm.
 - ii) All the partners, in case the firm is a partnership firm.
 - iii) The person duly authorised by the Board of Directors of the Private Limited or Limited Company.
- 2) In case the applicant Company is a Private Limited or Limited Company, a copy of minutes of the Board of Directors
- 3) If Partnership firm, list of names and addresses of all partners. List of Board of Directors of Private Limited or Limited Company with full names and addresses of all directors.
- 4) Attested copy of registration certificate from District Industries Centre if the applicant firm is a Small Scale Unit.
- 5) Partnership deed copy if partnership firm.
- 6) Address proof of the authorised applicant/proprietor (Voter I.D, Driving license)
- 6) Documents for Manufacturing Chemist Employed (not applicable if the license is required on Form 37 for a testing laboratory):
 - i) Affidavit duly attested by Public Notary
 - ii) Attested copies of educational certificates, experience certificates.
 - iii) Attested copy of the letter of approval by State Drugs Controller.
 - iv) Copy of consent letter, appointment letter or joining letter.

- v) Medical certificate from a registered medical practitioner along with the eye fitness certificate.
 - vi) Four photographs per applied license
 - vii) Address proof
- 7) Documents related to Analytical Chemist Employed:
- i) Affidavit duly attested by Public Notary
 - ii) Attested copies of educational certificates, experience certificates
 - iii) Attested copy of the letter of approval by State Drugs Controller
 - iv) Copy of consent letter, appointment letter or joining the letter
 - v) Medical certificate from a registered medical practitioner along with the eye fitness certificate.
 - vi) Four photographs per applied license
 - vii) Address proof
 - viii) Attested copy of the consent of Approved testing laboratory that tests those raw materials and finished products which require sophisticated instruments for analysis
 - ix) Three copies of the Plan of Premises showing all the sections and dimensions.
 - x) Documentary proof of ownership or rental basis of the proposed premises. Copy of rental agreement in case of rented premises. Attested copy of ownership proof of rented premises from the property owner
 - xi) Copy of No Objection Certificate from Pollution Control Board.
 - xii) In case of renewal of license attested copy Air and Water Consent from the Pollution Control Board (not applicable if the manufacturing unit is exempted for the same).
 - xiii) Copy of test report of water from a Government Approved Laboratory regarding its portability and freedom from pathogenic microorganisms

13.3.2. Licenses

Type of Manufacturing License	Application Form to be Submitted
For drugs other than those mentioned in Schedules C , C (1) and X	Form 24
For Homeopathic Medicines	Form 24C
For drugs mentioned in Schedule X and not specified in Schedules C & C(1)	Form 24F
For drugs mentioned in Schedules C and C (1) excluding those specified in Schedule X	Form 27
For loan license for drugs mentioned in Schedules C and C (1) excluding those specified in Schedule X	Form 27A
For drugs mentioned in Schedules C, C(1) and X	Form 27B
For the manufacture of drugs for the purposes of examination, test or analysis	Form 30
For approval for carrying out tests on drugs/cosmetics or raw materials used in the manufacture on behalf of licensees for manufacture for sale of drugs/cosmetics	Form 36

13.3.3. Renewals

For renewal certificate of drug manufacturing Licences from this Directorate the applicant should follow procedure given below:

1. For obtaining renewal Licence in Form 26 applicant should fill Form 24/Form 27 along with additional information data. The Forms and the list of all the documents that needs to be submitted may be obtained from the Food & Drugs Administration department or it can also be downloaded from link below.

List of Documents to be Submitted for Grant of Manufacturing Licence Drug Forms

2. Applicant to pay the necessary fees vide E-challan to be paid to Head of accounts, Demand No. 53; 201 Medical and Public Health, 04 Public Health, 104 Fees and Fines, 01 Fines. Fee structure can also be downloaded from link:

Fee Structure

3. For generation of E- challan applicant needs to fill the challan form available with the department for requisite fees and get it verified from Drugs Inspector and submit it to accounts section where E-challan will be generated and issued to the applicant. Generated E-challan to be paid in the Treasury branch of State Bank of India.
4. Applicant needs to submit all the documents mentioned in the list including original copy of challan paid towards the fees to entry clerk in the inward section.

File Movement once it is Submitted in Entry Section is as Under:

1. Hard copy of application received in the inward Entry section.
2. Entry clerk forwards the file to Accounts section of the Department for verification of amount paid through challan.
3. The Accounts Section after verification of amount forwards the file to concerned dealing hand.
4. The dealing hand registers the application and scrutinises all the documents and puts up to the Technical Officer.
5. The Technical Officer scrutinises the document submitted and also verifies the product list requested under the said licences; and puts comments and forwards the file to the next supervisory Officer that is either Assistant Drugs Controller (ADC) or the Dy. Director, (Dy. Dir) as the case may be.
6. The ADC or the Dy. Director; reviews the comments / note submitted by the Technical Officer and puts additional comments depending on his/her observations if any and forwards the scrutinised application to the Director; who is the Licensing Authority; with recommendation; depending upon the observation made such as:
 - a. The deficient documents to be called.
 - b. Certain clarifications required in the product permission sought.
 - c. Director (Licensing Authority) on perusal agrees to the recommendations made; and application is sent to the concerned dealing hand.
 - d. Premises to be inspected to consider Renewal application.
7. Director gives his directions & sends file to dealing hand.
8. In case of recommendations such as a, b, c the concerned dealing hand, puts up a draft of letter conveying the observation and calling up for compliance from the licensee and forwards to the Technical Officer. In case of recommendations at (d) dealing hand puts up the application to the concerned Drugs Inspector for inspection of the premises.

9. In case of recommendations such as a, b, c the Technical Officer forwards the draft to the next superior i.e. the ADC/Dy. Director; who in turn forwards to the Director who approves the draft and send backs to the application file to the concerned dealing hand. In case of observation at d; the Drugs Inspector along with the supervisory officer, ADC/Dy. Director conducts the inspection of the premises for renewal of licences and submit the report to the Director.
10. In case of recommendations such as a, b, c the dealing hand puts up the file with letter communicating the deficiency; to the Technical Officer.
11. The Technical Officer countersigns the same and puts up to the ADC/Dy. Director.
12. The ADC/Dy. Dir. again countersigns and forwards it to the Director for sign.
13. The Director signs the letter and sends the file to Dispatch clerk for dispatch.
14. The Dispatch clerk gives the outward no.; prepare and sends it to the post for delivery.
15. In continuation to step 09; Director peruses the report and then agrees to the recommendation which is either; it is recommended to either.
 - (a) Grant the Renewal Certificate; or
 - (b) To call for compliance of certain deficiencies.
16. In case of (b) the dealing hand puts up the file with letter communicating the deficiency; to the Drugs Inspector.
17. The Drugs Inspector countersigns the same and puts up to the ADC/Dy. Director.
18. The ADC/Dy. Dir. again countersigns and forwards it to the Director for sign.
19. The Director signs the letter and sends the file to Dispatch clerk for dispatch.
20. The Dispatch clerk gives the outward no.; prepares and sends it to the post for delivery.
21. In continuation to step 15; if grant of renewal of licence is recommended; then the dealing hand puts up the draft of the licence to be issued; along with the covering letter; and the list of products permitted with endorsement; to the Drugs Inspector.
22. The Drugs Inspector verifies the draft for correction and puts up to ADC/Dy. Dir.
23. The ADC/Dy. Dir. Countersigns and puts up to the Director.
24. The Director approves the draft and sends to the dealing hand.
25. The dealing hand prepares the fair renewal certificate along with the list of products and puts up to Drugs Inspector.
26. Steps from 17, 18, 19 & 20 are repeated.
27. After compliance of the deficiencies as regards steps 15(b) are submitted by the applicant; dealing hand puts up the file to the concerned Drugs Inspector.
28. The Drugs Inspector verifies the compliance submitted and puts up the noting depending upon the observations made and puts up the file to the ADC/Dy. Dir with recommendation either for grant of licence or for verification of the compliance submitted by visiting the premises.
29. The ADC/Dy. Dir. Puts up their comments and forward the file to DFDA.
30. The DFDA agrees to the recommendations and sends back the file to the dealing hand.
31. The dealing hand depending upon whether it is recommended for grant of licence or for re-inspection; puts up either the draft of the renewal certificate or the file directly to the drugs Inspector.

32. The Drugs Inspector along with ADC/Dy. Dir. Re-inspect the premises and submit their report to the Director with recommendation for grant of licences.
33. Steps from 21 to 25 are repeated.
34. The Drugs Inspector countersigns the renewal certificate and puts up to ADC/Dy. Dir.
35. The ADC/Dy. Dir. Countersigns the renewal certificate and puts up to DFDA for sign.
36. The DFDA signs the licence and sends it to Dispatch clerk for dispatch.

13.4. GRP IN WHOLESALE BUSINESS

13.4.1. Documentation

A licence is required to sell, stock, exhibit for sale, or distribute drugs. In order to open a retail drug store in any state, the following documents are needed for a new licence:

- 1) **Application** (in duplicate) on Form 19 of the Drugs and Cosmetics Rules, 1945. One copy is for biological drugs and the other is for non-biological drugs.
- 2) A fee of ₹1500 per licence (total ₹3000) to be deposited in State Bank of India/Government Treasury under specific head for grant of a retail sale licence.
- 3) The following documents should be carried with the qualified person while submission of the fee:
 - i) An attested copy of Diploma in Pharmacy from any institution duly recognised by Pharmacy Council of India,
 - ii) An attested copy of registration certificate issued by State Pharmacy Council,
 - iii) An attested copy of matriculation certificate, and
 - iv) Affidavit from the qualified person in case he/she is an employee of a drug store.
- 4) Affidavit on non-judicial stamp paper, duly attested by a first class magistrate by each partner in case of partnership concern or by the proprietor in case of proprietorship concern.
- 5) A **map** of the retail drug store duly signed by proprietor/partners of firm.
- 6) **Rent receipt** in case of rented premises or an affidavit to that effect if the person is the owner of the premises.
- 7) A **copy of the partnership deed** in case of partnership concern.
- 8) Refrigerator **purchase receipt**.

The licence is valid for a period of five years. It is required to be renewed for next five years before its expiry. Pharmacy Council of India is planning to make it mandatory to wear a white coat bearing the name of the registered pharmacist who is running the retail pharmacy.

13.4.2. Licenses

- 1) **General Licenses:** These licenses are granted to an individual having premises for the business and who may employ or may himself be a qualified person to supervise the sale of a drug store. Form 20 deals with license for retail sale of drug store, other than those specified in schedule C, C1, and X. For drug specified in schedule C, C1 excluding those specified in Schedule X is governed through form 21 and for Schedule X in 20F. The conditions applicable for general licenses are:

- i) The owner should display the license in a prominent place within the premises allowing public to see.
 - ii) The license should fulfill all the provisions of Drug and Cosmetics Act and Rules.
 - iii) Any change in the staff should be brought in the knowledge of the Licensing Authority within a month.
 - iv) Schedule C and C1 drugs should be stored as per the precautions prescribed by the Licensing Authority.
 - v) The owner should take permission from the License Authority for the sale of additional categories of drug listed in Schedule C and C1, excluding X.
- 2) **Restricted Licenses:** These licenses are granted for the restricted sale of drugs other than those specified in Schedule C, C1, and X and those specified in Schedule C and C1, excluding X are governed by the form 20A and 21A, respectively. The conditions for restricted licenses are:
- i) The drug should be sold in its original container.
 - ii) The license should fulfill all the provisions of Drugs and Cosmetics Acts and Rules.
 - iii) The drug should be purchased from a duly licensed dealer.
 - iv) The licenser should bear premises equipped with required storage facilities for drug.

13.4.3. Renewals

For obtaining Retail/Wholesale drug Licences from this Directorate the applicant should follow procedure given below. The renewal certificates are issued online by the Department.

1. To obtain renewal certificates in Form 21C (for Allopathic Drugs/ Schedule X Drugs), 20-E (for Homoeopathic drugs) applicant should fill form 19, 19B and 19C respectively and form for Additional information data. The application forms may be downloaded from link below:

Drug Forms

2. Applicant should pay the necessary fees vide E-challan. The fee of Rs. 3000/- with additional fee of Rs 250/- for Homoeopathic Licence and Rs. 500/- for Schedule X licence needs to be paid to Head of accounts, Demand No. 53; 201 Medical and Public Health, 04 Public Health, 104 Fees and Fines, 01 Fines. Fee structure can also be downloaded from link below:

Fee Structure

3. Using Firms login ID and Password provided, Licensee have to login to <http://www.xlnindia.gov.in> and create new application by clicking on "New Inward" and upload the required documents as per the sales guidelines; which will be available once the applicant logs in to xlnindia web application; and e-send the application.
4. After generating full application, take print out of software generated applications i.e. Form 19/19B/19C. For future reference; note down the inward ID that is generated on the system which will be generated only when full application is completed. The Inward ID generated is required to be mentioned on the covering letter while submitting hard copies of the application.

5. Submit hard copy of all documents, along with original copy of e-challan paid towards the fees to the entry clerk in the inward Section within 72 hours of e-send of application.

File Movement once it is Submitted in Entry Section is as Under

1. Hard copy of application received in the inward Entry section.
2. Entry clerk forwards the file to Accounts section of the Department for verification of amount paid through challan.
3. The Accounts Section after verification of amount forwards the file to concerned dealing hand.
4. The dealing hand places the application in the file of the licensee maintained in the department and scrutinises all the documents and puts up to the Director for allotting to the Drugs Inspector/ADC.
5. The Director peruses the application and marks it to any Drugs Inspector/Asst. Drugs Controller for further processing; online. The hard copy also moves; as the online application moves.
6. Drugs Inspector/ADC will scrutinise the documents and accordingly inspect the premises. Drugs Inspector/ADC will propose for grant of renewal certificate if relevant documents are submitted and the premises were found satisfactory on inspection.
7. Depending on the observations during inspection, Drugs Inspector/ADC will propose
 - a) Grant of renewal certificate.
 - b) Issue of Show cause letter.
 - c) Issue corrective letter.
 - d) and forwards the file to Assistant Drugs Controller /Deputy Director.
8. Assistant Drugs Controller /Deputy Director will put recommendations and forward the file to the Director.
9. In case of 7(a) the final Renewal Certificate are granted by the Director ie. Licensing Authority. And file is sent to the Dispatch Clerk.
10. In case of 7(b) Licensee gives clarification offline as a hard copy to the entry Clerk as well as online.
11. Application is handed over to the Dealing Hand by the Entry Clerk.
12. Dealing Hand files the clarification and forwards the file to the Drugs Inspector.
13. If Licensee gives a) satisfactory clarification/reply, then the Drugs Inspector will propose for grant of renewal licences and put up the file to concerned Assistant Drug Controller/Dy. Director, which is also recorded online.
b) If clarification found not satisfactory; then the Drugs Inspector will propose for personal hearing by the Director and forward the file to Assistant Drugs Controller /Deputy Director.
14. Assistant Drug Controller/Dy. Director will put up the file for Director with his comments.
15. In case of (a), Director will grant the Renewal Certificate to the Licensee, final certificate is issued by the Director online. Incase of (b), Licensee is called for personal hearing.

16. In continuation of 13(a) the e-signed licence is printed and forwarded to Dispatch clerk. In case of 13(b) after personal hearing Warning/Suspension is issued to the Licensee.
17. Licensee shall collect the Renewal Certificate from Technical Section of Directorate of Food & Drugs Administration.

13.5. IMPORT AND EXPORT OF DRUGS AND MEDICAL DEVICES

13.5.1. Introduction

In the field of pharmaceutical industry, India is ranked 3rd in the world. Despite of its strong position in the pharmaceutical market and increasing economy, a well-developed research and development programme is out of reach for a variety of reasons. To avoid this situation, India has opened its pharmaceutical market to MNCs and supports import and export of drug throughout the country.

Through 11 port offices situated across the country, the Central Medicines Standard Control Organisation (CDSCO) regulates the import and export of drugs in the country. Following rules and acts govern the manufacture, sale, import, export, and clinical research of drugs in India:

- 1) Drugs and Cosmetics Act, 1940 and Rules, 1945.
- 2) Pharmacy Act, 1948.
- 3) Drugs and Magic Remedies Act, 1954.
- 4) Medicinal and Toilet Preparation Act, 1956.
- 5) Narcotic and Psychotropic Substances Act, 1985.
- 6) The Drugs (Prices Control) Order, 1995.

13.5.2. Documents and Licenses for Import of Drugs

Form and Manner of Application

1. Import License:

- (1) An application for an import License shall be made to the licensing authority in Form 8 for drugs excluding Schedule X, and in Form 8-A for Schedule X drugs; either by the manufacturer or by the manufacturer's agent in India who is having the wholesale license for sale or distribution of drugs and shall be accompanied by a License fee of 1000 rupees for a single drug and 100 rupees for each additional drug and by an undertaking in Form 9 duly signed by or on behalf of the manufacturer.
- (2) Any application for import license in Form 8 or 8-A, which shall be accompanied by a copy of Registration Certificate issued in Form 41 under Rule 27-A; in case of emergencies the issue of Import License by the central government in Form 10 or 10-A without issuance of Registration Certificate under Rule 27-A, for reasons to be recorded in writing.
- (3) A fee of 250 rupees shall be paid for a duplicate copy of license, if the original is defaced, damaged or lost.

2. Registration Certificate:

- (1) Application for issue of a Registration Certificate shall be made to the licensing authority in Form 40, either by the manufacturer or authorised agent in India under this rule and shall be specified in the sub rule (3) and the information and undertakings specified in Schedule D-1 and Schedule D-II duly signed by on behalf of the manufacturer.
- (2) The authorisation by a manufacturer to his agent in India shall be documented by a power of attorney executed and authenticated either in India before a First Class Magistrate, or in the country of origin before such an equivalent authority, the certificate of which is attested by the Indian Embassy of the said country, and the original of the same shall be furnished along with the application for Registration Certificate.
- (3) (i) A fee of 1500 US dollars shall be paid along with the application in Form 40 as registration fee for his premises meant for manufacturing of drugs intended for import and use in I.
(ii) A fee of 1000 US dollars shall be paid along with the application in Form 40 for the registration of a single drug meant for import into and use in India and an additional fee at the rate of 1000 US dollars for each additional drug.
- (4) The fees shall be paid through a Chalan in the Bank of Baroda, Kasturba Gandhi Marg, New Delhi-110 001 or any other branch or branches of Bank of Baroda, or any other bank, as notified, from time to time, by the Central Government, to be credited under the Head of Account "0210-Medical and Public Health, 04-Public Health, 104- Fees and Fines".

In case of any direct payment of fees by a manufacturer in the country of origin, the fees shall be paid through Electronic Clearance System (ECS) from any bank in the country of origin to the Bank of Baroda, Kasturba Gandhi Marg, New Delhi, through the Electronic Code of the bank.

- (5) The applicant shall be liable for the payment of a fee of 5000 US dollars for expenditure as may be required for inspection or visit of the manufacturing premises or drugs, by the licensing authority or by any other persons to whom powers have been delegated in this behalf by the licensing authority under rule 22.
- (6) The applicant shall be liable for the payment of testing fee directly to a testing laboratory approved by the Central Government in India or abroad, as may be required for examination, tests and analysis of drug.
- (7) A fee of 300 US dollars shall be paid for a duplicate copy of the Registration Certificate, if the original is defaced or damaged.
- (8) No Registration Certificate shall be required under these rules in respect of an inactive bulk substance to be used for a drug formulation, with or without Pharmacopoeial conformity.

13.5.3. Documents and Licenses for Import of Medical Devices

Registration of Medical Devices for Import

1. Application for Registration Certificate in respect of the premises and the devices manufactured by the manufacturer and meant for import into India is required to be made by the manufacturer or importer or his agent in India, in

- Form 40 and in form and manner as under Rule 24A of the Drugs and Cosmetics Rules. The application addressed to the Drugs Controller General (India) shall be deposited at the CDSCO, FDA Bhawan, Kotla Road, Near Mata Sundari College, ITO, New Delhi-110002.
2. A fee of US\$ 1500 or its equivalent shall be paid alongwith the application as registration fee for the premises where the devices, intended to be imported are being manufactured by the manufacturer.
 3. A fee of US\$ 1000 or its equivalent shall be paid for registration of single Medical Device (which may include variation in sizes or shape without any change in the material or method of use) and an additional fee US\$1000 for each additional device shall be paid.
 4. The fee shall be paid through a challan in the Bank of Baroda as prescribed under the said Rules.
 5. The informations and undertakings required to be furnished under Schedule DI and DII may be modified to suit the requirements of devices in place of normal pharmacological products. The information shall include the following details:-

(A) Applicant Details:

1. Applicant's company name, address and contact number.
2. Name and address of foreign manufacturer (Manufacturing premises).
3. Copy of the Plant Master File.
4. Name and address of the local authorised representative.
5. Name and address of the importer.
6. Local manufacturer, if any processing is being done in the country.

(B) Product Information:

- 1) Proprietary/Brand name.
- 2) Brief description of the device.
- 3) Category of device.
- 4) Intended use and method of use.
- 5) Medicals specialty in which the device is used.
- 6) Qualitative and quantitative particulars of the constituents.
- 7) Brief description of the method of the manufacture and specification of the materials used.
- 8) Contraindications, warnings, precautions potential adverse events and alternate therapy, wherever applicable.
- 9) List of accessories and other devices or equipment to be used in combination with the device. Other descriptive information, including accessories packaged with the product.
- 10) Variations in shape, style or size of the device, if applicable.
- 11) Labeling details conforming to Drugs and Cosmetics Rules, 1945.
- 12) Physician manual and promotional literature (Literature insert) in English.
- 13) Packaging description including pack sizes.
- 14) Recommended storage conditions.
- 15) Summary indications of any reported problems.
- 16) Details of standards to which the device conform alongwith the copy of the standard.

(C) Regulatory Status:

1. Approval of the product from any other regulatory agency (Separate evidence for the approval from the each agency)
 - (a) US FDA clearance/approval.
 - (b) EU medical device directive (CE Certificate).
 - (c) Australia/Canada/Japan approval.
 - (d) Approval in any other country.
1. Copy of ISO/EN Certification if any for the manufacturing facility.
2. List of countries where the device is being sold.
3. List of countries where device is withdrawn from sale with reasons, if any.

(D) Master File (Details of Good Manufacturing Practices Employed by the Manufacturer to Ensure Quality of the Device):

1. Component/Material used.
2. Device Master File.
3. Manufacturing process/Flow Chart.
4. Quality Assurance procedures/process controls.
5. Final product testing or design inputs/outputs verification, if applicable.
6. Functionality Test protocol and report, if applicable.
7. Risk Assessment as per ISO 14971.
8. Sterilization process and validation/verification.
9. Stability data or statement of established stability of material used as applicable.
10. Shelf life of the device.
11. Biocompatibility and Toxicological data, wherever applicable.
12. Device GMP Certificate.

(E) Devices Containing Medicinal Product

1. If device incorporates a medicinal product, which is liable to act upon the body with action ancillary to that of the device, data on the safety, quality and usefulness of the medicinal substance used.
2. Data on compatibility with medicinal products, if device intended to deliver medicinal products.
3. Clinical data and published articles, if any.
4. Batch Release Certificate for products incorporating any medicinal substance or substances of animal origin.
5. For devices not approve for marketing in the country of origin, the applicant shall submit reports of clinical trials, details of sales, certificates of satisfactory use from the medical specialists about the use of the device and details of product complaints, if any.

(Medical Devices with prior approval from any of the recognized regulatory authorities will be subjected to an abridged evaluation and only a summary of all the studies and information described above is to be submitted)

(F) Post Market Surveillance:

1. Procedures for distribution of records.
2. Complaint handling.
3. Adverse incident reporting.
4. Procedure for product recall.

(G) Undertaking of Conformity With Respect to Product Standards, Safety and Effectiveness Requirements and Quality Systems in the Country of Origin.

5. The Registration Certificate shall be issued in Form 41 of the said Rules.
6. The application for import licence shall be made in Form 8 alongwith a fee of Rs. 1000/- in the Form and manner prescribed under the Drugs and Cosmetics Rules.

13.5.4. Documents and License for Export of Drug And Medical Device

1) General Requirements: Section 801(e)(1) of the FFDCA

- i) Meet specifications of foreign purchaser;
- ii) Not in conflict with laws of importing country;
- iii) Shipping package labeled as intended for export; and
- iv) Not sold, or offered for sale, in U.S. commerce. *Kanasco v. United States* (4th Circuit Case)

2) Export Under 802(b)(1) – “Tier One”

- i) Meets the requirements of Section 801(e)(1) of the FFDCA
- ii) Comports with the laws of the importing country;

3) Valid marketing authorization from a "tier one" country [= EU or European Econ. Area countries + Australia, Canada, Israel, Japan, New Zealand, Switzerland, S. Africa]

4) The drug is not adulterated in the following ways:

- i) Consists of any filthy, putrid, or decomposed substance; fdca § 501(a)(1)
- ii) Prepared, packed, or held under insanitary conditions that could result in contamination by filth or injury to health; or fdca § 501(a)(2)(a)
- iii) Container is composed of any poisonous or deleterious substance which may render the contents injurious to health; or fdca § 501(a)(3)
- iv) Strength, purity, or quality falls below that which it purports or is represented to possess; fdca § 501(c)
- v) Mixed or packed with any substance so as to (1) reduce its quality or (2) substitute for it wholly or in part fdca § 501(d)
- vi) Substantial conformance with gmps, or meets international quality systems standards recognized by fda; fdca § 802(f)(1)
- vii) Not an imminent public health hazard; fdca § 802(f)(4)
- viii) Labeled/promoted in accordance with requirements and conditions of: fdca § 802(f)(5)(a) (1) tier one country granting valid marketing authorization; and (2) the importing country;
- ix) Labeled in the language and units of measurement designated by the importing country; FDCA § 802(f)(5)(B)
- x) Export notification:
 - a) Listed country
 - b) Unlisted country
- xi) Record maintenance
 - a) Drugs exported
 - b) Countries to which devices exported.

Tier “Two” Countries: FDCA § 802(b)(2)

- 1) Don't have authorisation from one of the “Big 25”
- 2) But do:

- i) Meet the law of the destination country; and
- ii) Have valid marketing authorisation from responsible authority within the destination country

Tier "Three" Countries: FDCA § 802(b)(3)

- 1) Exporter provides FDA with "credible scientific evidence" that satisfies FDA as to the safety and effectiveness of the conditions of use in the destination country
- 2) Destination country "appropriate health authority" must:
 - i) Request FDA to approve the export
 - ii) Certifies that it understands that the drug isn't approved in U.S. or "Big 25"
 - iii) Concur that the "credible scientific evidence" for use in its country

Export under 802(c) - Drugs for Investigational Use

Export under 802(d) - Anticipation of Marketing Authorisation

Export under 802(e) - Diagnosis, Prevention, or Treatment of Tropical Disease.

i) FDA Approved Application: Risk/Benefit Determination

ii) Reporting Requirements: Adverse Events or Diversion

- 1) **Export Notification and Recordkeeping Requirements:** Dec. 19, 2001 Federal Register notice (66 Fed. Reg. 65429).
- 2) Adds new regulation – 21 CFR §1.101 -- have to keep a record of all the devices or drugs exported under §802(b), including:
 - i) records showing the product met the foreign purchaser's specs
 - ii) records showing the product does not conflict with foreign company's specifications
 - iii) records showing the product was labeled on outside with a statement that it was intended for export.
 - iv) Records to show the product is not offered for sale in the U.S. e.
 - v) Extra rules for partially processed biologics

Certificates For Export – In Compliance FDCA § 801(e)(4)

- 1) Certificates to Foreign Government
- 2) Certificate of Exportability

Export Regulations of India

Registration

- 1) It was compulsory for every exporter to obtain an exporters' code number from the Reserve Bank of India before engaging in export.
- 2) Registration with Regional Licensing: Authorities (obtaining IEC Code Number) The Customs Authorities will not allow you to import or export goods into or from India unless you hold a valid IEC number.
- 3) For obtaining IEC number you should apply to Regional Licensing Authority in duplicate. Before applying for IEC number it is necessary to open a bank account in the name of your company / firm with any commercial bank authorised to deal in foreign exchange. The duly signed application form should be supported by the following documents:
- 4) Bank Receipt (in duplicates)/Demand Draft for payment of the fee of 1,000 USD.
- 5) Two copies of Passport size photographs of the applicant duly attested by the banker to the applicants.

- 6) A copy of Permanent Account Number issued by Income Tax Authorities. If PAN has not been allotted, a copy of application of PAN submitted to Income Tax Authorities
- 7) The number should normally be given within 3 days provided the application is complete in all respects and is accompanied by the prescribed documents.
- 8) An IEC number allotted to an applicant shall be valid for all its branches/divisions as indicated on the IEC number

Acquire Export License

- 1) **Exports Free Unless Regulated:** The current Export Licensing Policy of the Government of India is contained in the new Import Export Policy and Procedures, 1997-2002 as amended.
- 2) It may be stated that all goods may be exported without any restriction except to the extent such exports are regulated by the ITC (HS) Classifications of Export and Import items

Application for an Export License: An application for grant of export license in respect of items mentioned in Schedule 2 of ITC (HS) Classifications of Export and Import items may be made in the form given in Appendix- 18A or 18B or 18C.

13.5.5. Renewal of Registration or Re-registration

The application is to be made 9 months before the expiry of the registration certificate, along with regulatory documentary compliance like Form 40, POA, GMP/COPP, registration certificate, DMF, license, etc.

1. Undertakings by the manufacturer or his authorised agent in India in respect of:
 - (i) Any administrative action taken due to adverse reaction, market withdrawal, regulatory restrictions, or cancellation of authorisation, not of standard quality report of any drug pertaining to this Registration Certificate declared by the Regulatory Authority of the origin country or by any Regulatory Authority of any other country, where the drug is marketed, sold, or distributed.
 - (ii) Any change in manufacturing process, packaging, labelling, testing, or documentation of any of the drug pertaining to this Registration Certificate.
 - (iii) Any change in the constitution of the firm, including name and/or address of the registered office/factory premises operating under this Registration Certificate.
2. Details of drugs imported in India during last 3 years.
3. Submission of original RC issued.

Requirements for Registration of Drugs in Form 10

- Covering letter
- Authorisation letter
- Form 8-Duly signed and stamped by the Indian agent along with the name and designation of the authorised signatory; Performa is enclosed at Annexure-XII.
- Form 9-Duly signed and stamped by the Indian agent along with the name and designation of the authorised signatory; if the form 9 is issued by the manufacturer, it shall be authenticated from Indian Embassy of the origin country; Performa is enclosed at Annexure-XIV.
- Requisite fees – 1000 for a proposed drug and ₹100 for each additional drug shall be paid at Bank of Baroda, New Delhi.
- Wholesale license.
- Registration certificate.

13.6. INSPECTION

13.6.1. Inspection of Premises Licensed for the Sale of Drugs

Given below are the duties of a drug inspector subjected to the instructions of the controlling authority:

- 1) He/She should inspect all the premises licensed for the sale of drugs in his area atleast twice a year in order to confirm whether or not the conditions of the license are being followed.
- 2) He/She should obtain and send drug samples for analysis. The samples can also be obtained from dealers or from persons who are conveying, delivering, or preparing to deliver any drug to a purchaser.
- 3) He/She should investigate any written complaints made to him, and to make such inspections and enquiries that are necessary to detect the sale of drugs in contravention of the Act and the Rules.
- 4) He/She along with his assistants should enter and search (at all reasonable times) all places, vessels, vehicles, or persons where or by whom an offence under the Act is believed to be committed.
- 5) He/She should order any person in possession of illegal drugs to not to dispose of such drugs for a period of not more than 20 days, or if the defect is such that it cannot be improved by the possessor, to seize the stock of the drugs.
- 6) He/She should institute legal proceedings if the Act and the Rules have been breached.
- 7) He/She should detain packages of imported drugs which are prohibited to be imported, only if he has been authorised by the State Government to do so.
- 8) He/She should exercise such other powers to give effect to the provisions of the Act and Rules.
- 9) He/She should maintain records of all inspections and also of the actions taken, including taking the samples and seizing stocks, and submitting copies of such records to the licensing authority.

13.6.2. Inspection of the Premises Licensed for the Manufacture of Drugs and Cosmetics

Given below are the duties of a drug inspector subjected to the instructions of the controlling authority:

- 1) He/She should inspect, not less than twice a year, all premises licensed for the manufacture of drugs (in the case of establishments licensed for the manufacture of Schedule C and C₁ drugs to inspect the plant, the process of manufacture, the means employed for standardising and testing of drugs), the methods and places of storage, details of location, construction and administration of the establishment and enquire into the technical qualifications of the staff employed, in order to satisfy himself that the provisions of the Act and the Rules are being observed.
- 2) He/She should obtain samples of drugs manufactured in the premises and send them for test or analysis.
- 3) He/She should check all records and registers need to be maintained under the Rules in order to satisfy himself that the provisions are being observed.
- 4) He/She should send detailed report of each inspection to the controlling authorities indicating how far the provisions of the Act and the Rules are being observed.

13.6.3. Documents to be Inspected

During the inspection, the pharmacy should provide access to:

- 1) All stock of dangerous drugs and devices;
- 2) All records of manufacture, sale, acquisition, receipt, shipment and disposition.

To streamline the inspection, you should have the following records readily available:

- 1) Past inspection reports
- 2) Pharmacy self-assessments
- 3) Copies of staff licenses
- 4) Master list of pharmacist and technician initials
- 5) DEA 222 forms
- 6) Power of attorney to execute DEA 222 forms
- 7) DEA biennial inventory
- 8) Drug take-back records
- 9) Wholesaler invoices
- 10) Records of drug returns
- 11) Records of destruction
- 12) Off-site records waiver
- 13) Pedigrees for drugs purchased
- 14) Inventory reconciliation reports
- 15) Controlled substances refill reports
- 16) **Policies:**
 - i) Quality assurance reports
 - ii) QA for medication errors
 - iii) Theft and impaired licensees
 - iv) Pharmacy technician job description
 - v) Pharmacist absence for meals
 - vi) After hours deliveries
 - vii) Interpretive services
 - viii) Repackaging previously dispensed drugs
 - ix) Automated Drug Delivery Systems
 - x) Common electronic files to prevent unauthorised release of patient
- 17) **Protocols:**
 - i) Refusing to dispense on ethical, moral, religious grounds
 - ii) Emergency contraception
 - iii) Nicotine replacement
 - iv) Advanced practice pharmacist
 - v) Procedures performed pursuant to BPC section 4052.2

Additional documentations and issues that the inspector will review:

- 1) DEA registration
- 2) Drug expiration dates
- 3) Drug take-back receptacles
- 4) Hot/cold running water (separate from restroom)
- 5) Confidential waste disposal
- 6) Interpretive services poster
- 7) Notice to consumers poster
- 8) Restroom location
- 9) Patient consultation
- 10) Posted pharmacy license and renewal
- 11) Out-of-state licenses
- 12) Prescription labeling
- 13) Prescription records
- 14) Quarantine area for expired and recalled drugs

- 15) Refrigerator/freezer temperature
- 16) Security features
- 17) Staffing ratio
- 18) Transmission of CURES data
- 19) Wearing identification or name tag printed in at least 18-point type
- 20) Possession of keys to the pharmacy

13.6.4. Documentation after Inspection

After the inspection If the inspector orders a correction, you will be instructed how to submit a plan or proof of correction to the board within a specified period. Keep all documentation related to completing the correction order with the inspection report.

If the inspector suspects a violation of pharmacy law has occurred, you may receive a written notice. Depending on the type of violation, the board may:

- 1) Issue a letter of admonishment.
- 2) Issue a citation (with or without a fine).
- 3) Refer the case for disciplinary action against the pharmacy and/or individual licensee.

Letters of admonishment and citations are not considered to be discipline or disciplinary actions. You may contest a letter of admonishment or citation by requesting an informal office conference. In the case of a citation, you also may request a formal hearing before an administrative law judge. You will receive a letter from the board about the administrative action process, and you must reply by the specified due date.

13.7. E-GOVERNANCE IN GOOD REGULATORY PRACTICES

The Government of India is in the transition phase, moving from traditional paper mode to using Information and Communications Technology (ICT) in the governance process. The use of ICT in the governance process is called e-Governance. The Government of India has been increasingly focusing on the use of Information and Communications Technology (ICT) to overcome issues like red-tapism, lack of accountability and transparency in public services, lack of access to information, slow movement of files and other documents, ineffective delivery of public services etc.

13.7.1. Objectives of e-Governance

- 1) To exchange information with citizens, businesses, or other government departments
- 2) To provide efficient delivery of public services
- 3) To enhance internal efficiency of the government system
- 4) To reduce cost/increase the revenue
- 5) To re-structure the administrative processes and improve quality of services

13.7.2. Pillars of e-Governance

e-Governance is a holistic initiative with four key pillars: people, technology, process and resources.

Shivakumar in his paper explained basic structure of e-Governance as having four pillars (Kolachalam Shivakumar 2002):

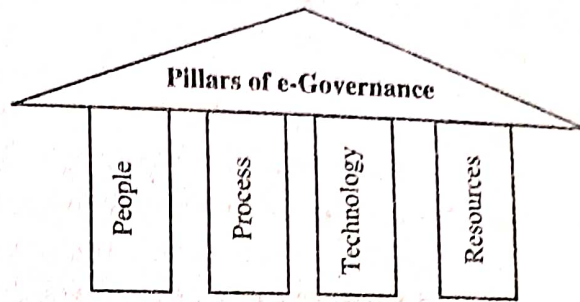


Figure 13.1: Pillars of e-Governance

- 1) **Leadership/Vision:** A clear vision and commitment among the leadership at the top of the government is needed.
- 2) **Governance/Administration:** Clearly defined policies around e-Governance and its implementation plan should be in place.
- 3) **Integration/Collaboration:** An efficient and effective collaboration among the key players is needed. These include government entities, private sector, academic institutions, businesses, Non-governmental Organisations (NGOs) etc. **Technology/Infrastructure:** Right infrastructure and technological developments should be made available and accessible to all the citizens.

13.7.3. Types of interaction in e-Governance

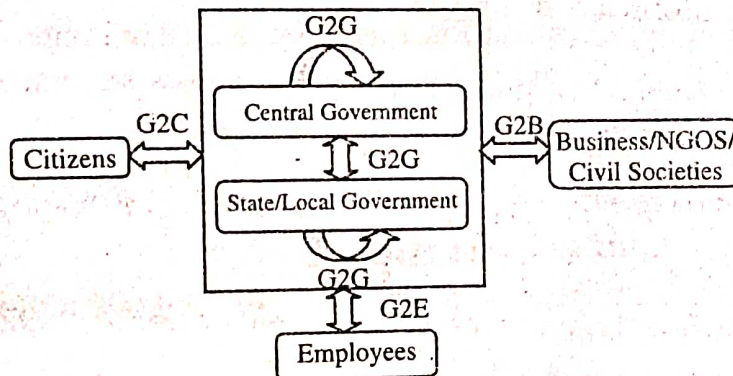


Figure 13.2: Type of Interaction in e-Governance

- 1) **G2G (Government to Government):** This type of interaction includes exchange of information electronically between the government bodies i.e. between national (central), state and local government and within the government entities at various levels. This type of interface helps in smooth and transparent functioning of the government processes along with saving time and being cost-effective as well. Examples of G2G services include inter-office teleconferencing, Online Budget System, Electronic stamping of bills etc.
- 2) **G2C (Government to Citizen):** This type of interaction includes exchange of information electronically between the government bodies and the citizens. This type of interface helps general public to access government services, information and provide feedback electronically. The aim is to make government services citizen-friendly. Examples of G2C services include passport/visa, property registration, birth and death certificate, marriage certificate, municipality services, death certificate etc.

- 3) **G2B (Government to Business):** This type of interaction includes exchange of information electronically between the government bodies and business entities, Non-governmental Organisations (NGOs) and civil societies. This type of interface helps cut down red-tapism and establishing business environment which is transparent, cost-effective and saves time. Examples of G2B services include e-Tender Box (ETB) system, e-Procurement Programme etc.
- 4) **G2E (Government to Employees):** This type of interaction includes exchange of information electronically between the government bodies and employees. This type of interface aims to CSD Working Paper Series: Towards a New Indian Model of Information and Communications Technology-Led Growth and Development e-Governance in healthcare sector in India Page 9 make interaction between employees and government fast, efficient and employee satisfactory. Examples of G2E services include E-payroll, E-training etc.

13.7.4. Guiding Principles for e-Governance

- 1) **Form Simplification and Field Reduction:** The forms used should be simplified and should be structured in a way to capture minimum essential information.
- 2) **Online Applications and Tracking:** Online applications with proper tracking mechanism should be developed.
- 3) **Online Repositories:** Online repositories e.g. for educational certificates, employment documents etc. should be used for improving convenience to the citizens.
- 4) **Integration of Services and Platform:** Integrated and interoperable services should be provided to the citizens and businesses by mandating sharing of data between the online services and platforms like Unique Identity Authority of India (UIDAI), Mobile Seva platform etc.

13.7.5. Benefits of e-Governance

- 1) Increase in transparency and accountability of the government administration
Cost reduction and growth in the revenue
- 2) Improved convenience to the citizens and businesses
- 3) Expansion in government outreach
- 4) Reduce red-tapism
- 5) Improved coordination between the government bodies at various levels
- 6) Enhanced efficiency of the government system
- 7) Improvement in satisfaction level of the general public with the government services
- 8) Empowerment of citizens through information access
- 9) Improved interaction with the business entities
- 10) Improved quality of citizen services
- 11) Better enforcement of law
- 12) Reducing digital divide and providing equal access to information
- 13) Creation and linkage of local and global online communities
- 14) Encourage innovative leadership styles
- 15) Promotes economic development by creating an enabling environment