CODES ON SALES AND DISTRIBUTION OF DRUGS, 2071

Preamble: With the intention of contributing to the public health service through effective sales and distribution of medicines throughout Nepal by maintaining their highest level of efficacy, public safety and quality, this Code is issued for the implementation of Drugs Act, 2035, and Drugs Registration Rule, 2038, rule 11.

CHAPTER – 1

Preliminary

1. **Name:** The name of this Code shall be 'Codes on Sales and Distribution of Drugs, 2071.'

2. **Commencement:** This Code shall come into force immediately.

3. **Definitions:** Unless the subject or the context means otherwise,

   1) Act: means Drugs Act, 2035.

   2) Department: means the Department of Drug Administration.

   3) Service: means the wholesale or retail sales and distribution of finished drug product, and sales and distribution after manufacturing or compounding of a drug at a local level, as well as provision of counselling and information about the distributed drug.

   4) Service Centre: means a retail or wholesale pharmacy that a person had it registered according to the Drugs Act 2035 with an aim to store and distribute the drug, or any institution or section under a hospital, which distributes and stores finished or intermediate drug for the hospital only.

   5) Service Area: means a geographical catchment area categorized as per the Act.

   6) Pharmacovigilance: means the collection and evaluation of information on adverse effects or side-effects resulting due to the intake or use of the drug, and the prompt reporting to a concerned industry, and the national pharmacovigilance centre and the Department**.**

   7) Prescription: means a necessary drug with description given by a physician or a recognized health worker for a treatment after the check-up of a patient and the diagnosis of a disease.

   8) Labelling: means an information sheet with identification, recommendation and direction of the distributed drug clearly stated.

   9) Refill: means the process of full or partial re-dispensing of drugs mentioned in a prescription according to the recommendation from a physician.

CHAPTER – 2

General Infrastructural Provisions to be Followed by the Service Centre

4. **The Service Centre should have managed the following physical arrangements for drug storage, sales & distribution, manufacturing, packing, labelling, record keeping, counselling and other works; however, the Service Centre that carries out**

manufacturing and compounding must, in addition to the following provisions, fulfil provisions stated in the Drug Manufacturing Codes.

1) **Building and Premise**: Based on the Service Area, nature and quantity of the drug, the Service Centre must arrange for a concrete building or, as required (at least of 120 square feet surface area) a room within the concrete building. The drug storage area must be away from direct sunlight, leak proof or damp free and safe from unwanted heat, and furthermore, must be protected from access and activity of an unwanted person. The following must be kept in mind while making such arrangements:

   A) The nature and quantity of the drug

   B) An appropriate arrangement for the storage of the drug that must be kept under lock and key as per the Drugs Act and Drug Standard Rule, 2040

   C) Drug sales and distribution room

   D) A dedicated place for documentation work

   E) A space for necessary reference materials regarding drug related information, technology, *et cetera*

   F) A space for the short-term collection of useless material

   G) An area for the drug and material that have expired, been recalled and needing to be returned

2) **Furniture and Storage Provision:** The Service Centre must store the available drugs on shelves in a scientific manner. Stored drugs or materials must be arranged in a clean and tidy manner safe from adverse effect of dust, smoke, humidity or heat. Necessary means, equipment, *et cetera* must be arranged for the storage of the drug according to its quality and quantity. In an area for the sales and distribution of the drug and counselling and manufacturing, the following furniture or necessary arrangements must be made at minimum:

   A) For sales and distribution room, one table and three chairs

   B) For record-keeping, one 3 feet x 6 feet cabinet

   C) Storage area for the drug and appropriate number of cabinets as necessary

   D) For the drug that has to be stored in a cold place, minimum of one refrigerator of appropriate capacity, but if a cold room has been arranged, this requirement is optional.

3) **Human Resource**: The Service Centre must be operated under the supervision of a Chief Pharmacist or a person qualified according to the Drugs Act. The responsibility of the operation and professionalism of the Service Centre lies with the Chief Pharmacist or the aforementioned qualified personnel. The pharmacist and official working at the Service Centre must follow professional code of conduct as well as fulfil the following requirements:

   A) Subject-related training regarding the sales and distribution and storage of the drug

   B) Job description of each staff

   C) Professional appearing dress, for example, a white or sky-blue apron and identity card

   D) Registration of the pharmacist or assistant pharmacist at Nepal Pharmacy Council and certificates of professional qualification as per the existing law

E) Proofs of routine health check-ups of the staff

F) Knowledge about drug-information, physician-prescription, drug storage process and technology

4) Additional Provision: The Service Centre must put up a sign board containing a firm or centre name, department registration number, and if professional membership is available, its indication number, visibly. The sign board shall not contain any advertisement or a sign of advertisement. The board cannot contain colourful pictures or information and at most, three different colours may be used considering the colours of the background and the information written on the board. A uniformity on appearance can be brought about through a professional agreement.

5. Quality Assurance System: In order to demonstrate the quality of the activities carried out by the Service Centre, a system to manage and document each activity must be established.

1) The Service Centre must have its own clear and apt quality policy. For all of the services, there should be a policy related to the goal, program, process, standard, Service Area, staff selection, training, customer satisfaction, drug that is damaged or need to be returned, self-assessment and documentation, and a work plan to implement it.

2) Arrangements should be made for the declaration and implementation of a service-policy on the nature and scope of the Service provided by the Service Centre.

3) There must be a clear policy to arrange for thematic training to build capacity to deliver good quality service maintaining high level of professionalism appropriate to time and the current law. There must be necessary reference book, the Internet for the staff involved in the Service to be continually informed, as well as, according to the Service Centre's quality policy, periodic training and regular recording on professional knowledge and social subjects such as humility, politeness and personal empathy, *et cetera*.

4) There must be a clear policy and procedure to handle complaints and grievances regarding the delivered Service fairly, so that the consumer may get the highest level of satisfaction.

5) There must be a declared policy and procedure in place to be followed when the drug is to be returned or recalled for any reason.

6) There must be a clear policy and procedure for the Service Centre to conduct at least two self-audits every year on the quality of the activity and procedure of the Service Centre. Trust must be gained through thematic improvement following the review of variation and deficiency between the quality policy and practice. The leadership and primary responsibility of this activity must be as per the aforesaid Code 3.

7) The following documents and records must be kept and stored safely in every Service Centre.

A) Comprehensive list of documents and records

B) Complete set of certificates and directives as per the existing law, such as: pharmacy registration certificate, license, codes and directives

C) Service operation record like purchase bill, sales bill, operational procedures

D) Quality protocol

E) Standard operating procedures

F) Operating protocol

G) Sanitation and cleaning record

H) Complaint handling record

I) Policy papers

J) Staff personal detail

8) It is considered appropriate for any Service Centre to participate in a program related to accreditation conducted by national and international quality audit institutions to be assured of own's standard of the Service.

CHAPTER – 3

General Procedural Provisions to be Observed by the Service Centre

6. Procurement and Inventory Management: The Service Centre must follow the following provision for the procurement and inventory management of the quality drug:

1) The drug and material must only be procured from a registered supplier or manufacturer. When procuring in this way, there must always be a name, batch number, expiration date, quantity and procurement bill along with for every drug as per pre-determined quality.

2) The Service Centre must pre-evaluate a supplier and transport arrangement for every drug to be procured, and when there is no adverse effect on the quality of the drug, decide on the supplier and transport arrangement, and maintain its record. Such evaluation must contain clear information pertaining to the supplier and transport arrangement, such as: name, address, phone number, along with certificate, authorized representation related to industry or manufacturing, professional and business terms and agreement.

3) Through a regular inspection of a pre-determined supplier or transport arrangement, there must be a continual demonstration of the quality of the distribution of the drug.

4) As per the principle of first expiry, first out (FEFO), the drug received first and expiring earlier must be distributed first for an appropriate attention to the proper use of the drug.

5) A bill of the sales and distribution of the drug and its permanent record must be made in a sales and distribution register (ledger) and kept in a secure manner for at least 3 years.

6) In order to be able to give an adequate attention to store management, sales and distribution work and drug information, an arrangement must be made as much as possible to limit brand or generic dosage form of the drug with the same property and use.

7) A procurement policy with a benchmark for a minimum shelf-life must be followed to procure only the drug with a remaining shelf-life at least 50% of the total shelf life or 1 year at the time of procurement.

8) For the evaluation, return or destruction of the drug that has expired, needs to be returned, recalled, and has been kept because of its suspicious quality for various reasons, a predeclared process must be followed and documented.

7. **Storage:** For appropriate storage of the drug available in the Service Centre, the following provision must be observed.

    1) Prior to storing the procured drugs in their respective areas, they must be quarantined to confirm their dosage form, quality, minimum shelf life and integrity as per the purchase order.

    2) Storage of each drug must be done according to the storage instruction as mentioned on the product or dosage form, and the evidence related to a storage area must be documented, such as: temperature, humidity, light related instructions.

    3) Shelves, cupboards, *et cetera* for the storage of the drug must be kept clean and tidy.

    4) An arrangement or technology for cleaning, insecticide or killing rodent must be followed according to a written process.

    5) A separate area must be arranged for the drug required to be kept separate securely as per the Drugs Act, 2035, and the keys to the area must be put under the custody of the Chief Pharmacist.

    6) The drug required to be stored in a cold place must be stored in a refrigerator at a temperature as directed; however, for the Service Centre where a cold room has been arranged, this arrangement must be taken as an option.

    7) As per the first expiry first out principle, the inventory of the drug must be checked from time to time, and the drug nearing expiry must be kept separately for its easy use, or if it needs to be returned, undertake a process towards it. For returning, a process according to the minimum shelf-life benchmark policy must be followed.

    8) If the stored drug expires, needs to be returned or destroyed, it must be stored separately with a label clarifying the condition of the drug.

    9) An expired and unusable drug must be a regularly listed as well as returned to a respective supplier or manufacturer, and when cannot be returned, must be destroyed according to a defined process. For the drug destroyed or returned in this way, a record with a reason must be kept.

8. **Pharmacovigilance:** Expected or unexpected side effects caused by the drug must be continually monitored. The Service Centre must participate in pharmacovigilance by following the following process:

    1) Information about drug related adverse effects and impact received at the Service Centre must be promptly reported to the Department of Drug Administration and manufacturer or its authorized representative.

    2) Based on the information received at the Service Centre or any other notice, if any drug appears fake or is of suspicious quality, it must not be sold or distributed and an arrangement must be made to send the information about this to the Department of Drug Administration as soon as possible.

9. **Prohibited:**

    1) Smoking and alcohol consumption are prohibited at all kinds of Service Centres that provide a pharmaceutical service.

2) If anybody is found to have violated the aforesaid code 9.(1), a legal action may be taken regarding it as an offence against the Drugs Act or existing law and rule.

CHAPTER – 4

Special Provisions to be Observed by the Service Centre Undertaking Retail Drug Sales & Dispensing of the Drug

10. In addition to the general infrastructural provision for the Service Centre laid out in Chapter – 2, a retail drug sales and dispensing centre must arrange and follow the below mentioned special provision:

A) An arrangement for a specified area for counselling service

B) Availability of an adequate space to demonstrate to a patient the method of taking the drug and information

C) An arrangement for at least one table and three chairs for counselling service

D) Patient record such as details of patient's health, treatment and counselling

11. In addition to the general procedural provision for the Service Centre laid out in Chapter – 2, the Service Centre undertaking retail drug sales and dispensing must arrange and follow the following special provision:

A) Prescription Handling: A prescription should be handled according to the following provisions to provide quality pharmaceutical service to a patient based on a prescription the patient brings according to the existing law:

1) After receiving a prescription given by a physician or a recognized health personnel, the Chief Pharmacist must check if the prescription contains the following must have information:

a) Patient's identity (name, age, sex)

b) Prescriber's name, address and council registration number as per the existing law

c) Diagnosis of the ailment (suspected or confirmed)

d) Drug's name, strength, dosage form, dosage and quantity

e) Direction to the patient

f) Refill information

g) Prescriber's signature and date

2) Based on the subjects as per aforesaid 8.(1), the Chief Pharmacist must study and decide on the following aspects for the suitability and completeness of the prescription:

a) Pharmaceutical and pharmacological

b) Suitability for the patient

c) Social, legal and economic

d) Completeness of the prescription

3) Prior to dispensing the drug according to the prescription provided by a physician or a recognized health personnel, drug's dosage form, drug-drug interaction, contraindication and instances of past drug-abuse by the patient must be evaluated in detail, and if necessary the prescriber must be informed for an improvement. On the prescription improved this way, the dispensing must be done mentioning reasons as well.

B) Dispensing: After the suitability and completeness of the prescription have been confirmed, the drug mentioned in the prescription must be dispensed following the following process:

1) Necessary quantity must be removed from the drug storage area as per the prescription. If there is a possibility of an adverse effect on the quality of the drug during such removal, an arrangement must be made to address it.

2) The drug removed must be examined for preparing a bill. Such a bill must contain the drug's name, strength, dosage form and if possible, batch number.

3) Dispensed drugs must be safely packaged and labelled. Such a label should contain the drug's name, strength, dosage form, dosage, batch number, expiration date, direction for use and storage, dispensing date, and the Service Centre's identity.

4) The drug must be dispensed in an efficient and reliable manner for customer satisfaction.

C) Patient Counselling: In order to ensure maximum health benefits from an appropriate use of the drug, the patient must be made aware of the use of the drug and its effect. While counselling the patient about the information and desired effect of the dispensed drug, the following directions must be followed:

1) While dispensing the drug at the Service Centre, the following information and suggestion regarding the use of the drug must be given to support the appropriate use of the drug:

   a) Method of intake

   b) Duration of intake

   c) Intake schedule (how many times in a day, with food, after meal, before meal or in an empty stomach)

   d) Food or drink to avoid

   e) Expected but general side-effects

   f) Prescription for missed doses

   g) Other precautions

2) A separate area must be allocated for counselling. This is so that adequate attention can be given to patient's sensitivity and a space necessary for the Service delivery.

3) Counselling may be given orally or in writing or both ways, however, as much as possible written suggestion should be given such that the patient may understand it.

4) There must be an evaluation of whether or not the patient is properly following the counselling related to the drug. If found not being properly followed, an initiative should be taken to correct it as much as possible.

5) The Service Centre must keep the record of treatment of one's patient client. These records must contain consumed drug's dosage, strength, duration, drug allergies, drug

adverse-effects, drug dependence, drinking, smoking habit, problem faced during drug intake, and counselling done from time to time, and such a record must be maintained for at least 3 years.

6) A patient treatment record must be kept confidential and cannot be given or informed about to anyone without the patient's consent, however, it can be used for the benefit of the patient.

7) It is the responsibility of every Service Centre to provide information pertaining to other healthcare besides that of dispensed drug. One's client must be informed about local health promotion, household remedy, self-treatment system.

8) Since patients with chronic illness need to have regular health check-up, records of such patients must be kept separately, the patients counselled from time to time, and if necessary, an arrangement made to inform them when any suitable opportunity for a health check-up arises.

D) Pharmacovigilance: In addition to the Code that generally needs to be followed regarding pharmacovigilance, the retail drug sales and dispensing centre must evaluate general and severe forms of adverse effects based on the patient's treatment record and information obtained locally, and inform the Department of Drug Administration and a concerned supplier or manufacturer about them.

CHAPTER – 5

Special Provisions to be Observed by Service Centre Undertaking Wholesale and Distribution of the Drug

12. In addition to the general infrastructural provision stated in Chapter – 2, which the Service Centre wholesaling and distributing the drug must manage, the following provisions must also be managed:

A) An arrangement of separate areas for the drug storage, packing and labelling area and administrative and commercial activity operation and document storage

B) An arrangement for a sufficient space for packing and transportation of the drug

C) Appropriate instruments to regularly monitor temperature and humidity of the storage area

D) Necessary carton, tape and other materials of appropriate quality for the purpose of packing the drug

E) A sufficient area to separately stock the drug of suspicious quality that are not to be sold and distributed

13. In addition to the general procedural provision stated in Chapter – 3, which the Service Centre wholesaling and distributing the drug must manage, the following provisions must also be managed:

1) The drug must only be supplied to organization or retail seller that have been registered or authorized according to the existing law, and while supplying in this way, it must be ensured whether or not physical, human resource and procedural infrastructure is available to maintain the quality of the drug.

2) An arrangement to pack and transport according to the property of the drug must be managed. A necessary record must be available to demonstrate the standard and evidence of such an arrangement.

3) A sales invoice must be issued with the distributed drug. Such an invoice must clearly mention the name, strength, quantity, dosage form, batch number, supplier and receiver addresses, and their record and list must be maintained properly.

4) While transporting the drug, there must be an arrangement made such that the drug's identity does not disappear, that it does not contaminate another drug, does not get contaminated with another drug, does not break, does not leak, does not get stolen, and is safe from heat, pressure, dampness, light, humidity or other undesirable effects and microbial growth.

5) An arrangement must be made for a prompt-supply to one's regular customers in case of an emergency need of the drug.

6) An excellent stock operation must be carried out by following first in first out process, and the drug nearing expiry, damaged and incomplete must be stored in a separate area, and such a drug must not be sold and distributed under any circumstance.

7) Drugs returned but faultless must not be sold until an appropriate decision has been taken. Reselling is possible by documenting an evaluation that establishes that there has been no effect on the quality of the drug when it was not under the custody of the supplier.

8) An organization that has to supply the drug in wholesale must train and inform the staff working in one's own or a customer's firm or organization on proper storage, transportation, dispensing and caring of the drug to be sold and distributed, and must arrange to carry out monitoring related to these. For such training, support can be sought from an authorized representative or a manufacturer's specialist.

14. Mandatory arrangement for the manpower for categorization and operation of the Service Centre according to the Code:

1) Following the implementation of this Code, based on the categorization, the operation of the Service Centres must be mandatorily done by the Chief Pharmacist or Assistant Pharmacist and authorized professional.

2) The categorization and operation of the Service Centre shall be as issued by the Department of Drug Administration from time to time.

3) It shall be understood that a decision and direction issued by the Government of Nepal regarding the categorization or manpower for the operation of the Service Centre have been based on this Code itself.

15. Certification of good pharmacy practice:

1) A firm or the Service Centre that follows this Code can apply for the certification of good pharmacy practice at the Department with a document specified by the Department.

2) Against an application as per Code 15(1), the Department can issue a certificate on good pharmacy practice in a specified format if found appropriate after an audit work.

16. Annulment: The implementation of this Code automatically annuls the Codes for Sales and Distribution of Drugs, 2040.