MINISTRY OF HEALTH OF UKRAINE
NATIONAL UNIVERSITY OF PHARMACY
THE DEPARTMENT OF THE ORGANIZATION AND ECONOMICS OF
PHARMACY

PRINCIPLE OF THE ORGANIZATION
OF PHARMACY

for the 1st year students

Kharkiv
2014
The department of the organization and economics of pharmacy
National pharmaceutical university

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For the foreign students of pharmaceutical faculty
The book includes the basic questions on the organization of pharmaceutical activity in modern conditions.
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THE ORGANIZATION OF PHARMACEUTICAL AID.
THE CHEMIST SHOP.

The good health of people is one of a nation’s greatest assets. The way a country cares for and builds up this assets gives a fair indication of how good social structure of that country is and what it’s advantages and achievements are.

The medical aid either in policlincs or in hospital and different kinds of prophylaxis are impossible without application of high effective medicines and good organized pharmaceutical service.

The organization and economics of pharmacy gives the basic principles of location and work of pharmaceutical entities and observed the problems of the rational used of limited recourses for pharmaceutical goods manufacture and distribution in order to satisfy the public’s needs in prophylaxis, health care and diseases treatment.

Pharmacy is the profession concerned with the preparation, distribution, and use of drugs. Members of this profession are called pharmacists or druggists. They were once called apothecaries. The word pharmacy also refers to a place where drugs are prepared or sold. Most pharmacies, sometimes called drugstores and chemists shops, sell a variety of products in addition to drugs.

The practice of pharmacy is the custody, compounding and dispensing of drugs, the provision of non-prescription drugs, health care aids and devices and the provision of information related to drug use. The mission of pharmacy practice is to provide medications and other health care products and services and to help people and society to make the best use of them. Comprehensive pharmacy service encompasses involvement in activities to secure good health and the avoidance of ill health in the population. When the treatment of ill health is necessary, the quality of each person’s medicine use process should be assured to achieve maximum therapeutic benefit and to avoid untoward side effects. This presupposes the acceptance by pharmacists of shared responsibility with other professionals and with patients for the outcome of therapy.
**Chemist shop**

The place where drugs are compounded, dispensed, stored and sold called a chemists shop. It is a shop which dispenses medical drugs and other health-related items. **Pharmacy** *(from grech. apotheke is storage, depository; from lat. officina - workshop)* is the establishment of health protection, functioning according to the license, making and/or retail realization of medicines and other pharmacy assortment. The practice of pharmacy within each state is regulated by the laws of the state, including the regulation of licensure for pharmacy practice.

Licensing is foreseen in Ukraine for the government control. The aim of licensing and standards is to protect public health by ensuring that medicines and medical devices meet definable standards of quality assurance and are manufactured in conditions that are clean and free of contaminants.

Procedure of licensing from one side gives a right to carry on pharmaceutical activity during the set period of time and from other – is the form of state control after this type of activity.

**A license** is the document of state standard which confirms the right of licensee to introduction of economic activity for certain term on conditions of implementation of the licensed terms.

**A licensee** is a management subject getting a license to realization of definite type of economic activity, subject to licensing.

To get a license to pharmaceutical activities a pharmacy establishment is to submit the following documents:

- an application in accordance with the established form;
- the Charter of a pharmacy establishment, containing the list of all types of pharmaceutical activities that are planned to be carried out by the pharmacy establishment;
- registration certificate of a pharmacy establishment to be issued by local government bodies;
documents that confirm the right to the use of given premises for the purpose of carrying out pharmaceutical activities;

documents that confirm the certification of specialists who will carry out pharmaceutical activities in a given pharmacy establishment;

conclusion of Interior Ministry bodies about the technical preparedness of given premises and their alarm system for the storage of poisonous and narcotic medicines and psychotropic substances, if this type of activities shall be provided for by the Charter of a pharmacy establishment;

conclusion of sanitary, epidemiological and fire inspection bodies that the premises fit into the types of activities, which are stipulated by the Charter of a pharmacy establishment.

Pharmacy functioning by the rules set by the current legislation. The task of pharmacy is to provide the population with the skilled, valuable and timely pharmaceutical aid in accordance with the current legislation and international standard „Good Pharmaceutical Practice” (GPP). Functions of pharmacy are: making of medicines on individual prescriptions and the clinic requirements (production function); realization of medicines on recipes and without them (trading function); organization of sanitary-informative activity among the population, pharmaceutical care and informative aid to the hospitals on pharmaceutical questions (informative function); providing of the first medical aid and the aid for the privilege category of population (social function).

The Structure of the Chemist Shop

One can see several departments in chemists shop. They are: prescription department, non-prescription department, ready-made drugs department, drugs store department.

A prescription department is the department for reception of prescriptions and delivery of drugs. At this department medicines are sold or made according to
prescriptions. There one may buy powders and pills, mixtures and ointment, tinctures and decoction as well as drops, suppositories etc.

At the non-prescription department one can see ready-made drugs, different things for medical care and medical herbs.

If the chemists is large it has ready-made drugs department where the ready-made drugs are sold under the prescriptions.

The aims of drugs store department are to organize: the provision of chemists with different drugs in time, the reception of the products, the storing of drugs depends on their storage conditions and the provision of all departments of chemists with everything they need. The period of storage of pharmaceutical production till the moment of its use is pharmacy storage.

The chemists shop includes an area for the preparation and manufacture of medicines and other drugs. An average chemists’ has a hall for visitor, assistant room and proper working rooms. It is usually a clean, well-lighted, and well-ventilated area, with clean and sanitary surroundings. All the area is used for the storage, manufacture, compounding, and dispensing of drugs. Also it may have an aseptic block if it has a prescription department. While working with sterile or potentially dangerous pharmaceutical products, pharmacists usually wear gloves and masks and work with other special protective equipment. There must be a room which pharmacists used to produce infusions and decoctions, to wash and dry dishes, to distil water.

The pharmacy personnel. Pharmacy staff can be divided into the following groups: administrative (management), manufacturing (pharmaceutical), and additional. Administrative and management personnel includes the head of the pharmacy, his deputies, heads of departments, heads of pharmacy points and booths, accounting staff, economists and lawyers.

Pharmaceutical staff includes a pharmacist for receiving of prescriptions and dispensing pharmacist who manufacture intrachemists’ preparations, pharmacist who
provides informative work, pharmacist-analyst, senior pharmacist, pharmacist in pharmacy points and booths.

For pharmaceutical personnel include also a pharmacist for the production of medicines, the pharmacist on dispensing drugs without prescriptions, pharmacist on dispensing of herbal plants.

In general, the pharmacy must be staffed by at least two specialists who have appropriate education and meet one qualification requirements. For the production pharmacies it should be three specialists.

Additional staff - this is packers and cleaners. Pharmacy’s staff must meet uniform eligibility requirements, continuously improve their professional level (not less than five years held training (retraining)) and systematically provide a medical examination, to have special clothes and footwear.

In addition, the organizational structure of the isolated pharmacy includes such structural subdivisions - pharmacy point and pharmacy booth, which are established and functioned with a pharmacy.

**Pharmacy point** - structural unit of the pharmacy, which is created in the health facilities for trade by ready-made drugs, both prescription and OTC. The total area of a pharmacy point must be not less 18 m². The room is equipped with a drugstore shelves, cabinets, refrigerator, safe or metal cabinet for storage of poison drugs. The room must make way for sanitizing hands, a case for the separate storage of personal and protective clothing, storage cabinet for household equipment.

**Pharmacy booth** - a structural subdivision of the pharmacy, which is created on the territory of enterprises, establishments and organizations for retail realization of ready-made drugs that are sold without a prescription only. The presence of a prescription drugs in pharmacy booth is a violation of licensing conditions. The minimal area of pharmacy booth depends on its spatial location. If the pharmacy is located in the capital construction of the plant, factory, train station, airport, and the surface area shall be not less than 8 m², without a hall for visitors. In public buildings in the presence of a separate entrance (summing up the communication sewerage and
water supply systems, the presence of ventilation) the area of pharmacy booth must be not less than 21 m$^2$, including 10 m$^2$ - a hall for visitors, 3 m$^2$ - toilet. The pharmacy booth is equipped with pharmacy shelves, cabinets, refrigerator and place for the sanitization of hands, a case for the separate storage of a personal and protective clothing, closet for storage of household equipment.

**Pharmacists’ duty**

Pharmacists dispense drugs prescribed by physicians and other health practitioners and provide information to patients about medications and their use. They advise physicians and other health practitioners on the selection, dosages, interactions, and side effects of medications. Pharmacists also make quality and quantity control of the extemporaneous drugs and organize the condition for drugs storage. The interrelations between subjects of healthcare system are shown in scheme 3.

Scheme 3

*Supply and demand interaction in healthcare*

Pharmacists in community or retail pharmacies counsel patients and answer questions about prescription drugs, such as those about possible adverse reactions or interactions. They provide information about over-the-counter drugs and make recommendations after asking a series of health questions, such as whether the customer is taking any other medications. They also give advice about durable medical equipment and home healthcare supplies. Some community pharmacists provide specialized services to help patients manage conditions such as diabetes, asthma, smoking cessation, or high blood pressure.
Pharmacists in hospitals and clinics dispense medications and advise the medical staff on the selection and effects of drugs. They may make sterile solutions and buy medical supplies. They also assess, plan, and monitor drug programs or regimens. They counsel patients on the use of drugs while in the hospital, and on their use at home when the patients are discharged. Pharmacists also may evaluate drug use patterns and outcomes for patients in hospitals or managed care organizations. Pharmacists who work in home healthcare monitor drug therapy and prepare infusions—solutions that are injected into patients—and other medications for use in the home. Some pharmacists specialize in specific drug therapy areas, such as intravenous nutrition support, oncology (cancer), nuclear pharmacy (used for chemotherapy), and pharmacotherapy (the treatment of mental disorders with drugs). Pharmacists are responsible for the accuracy of every prescription that is filled, but they often rely upon pharmacy technicians and pharmacy aides to assist them. Thus, the pharmacist may delegate prescription-filling and administrative tasks and supervise their completion. Consultant pharmacists may travel to nursing homes or other facilities to monitor patient’s drug therapy.

Pharmacy technicians help licensed pharmacists provide medication and other healthcare products to patients. Technicians usually perform routine tasks to help prepare prescribed medication for patients, such as counting tablets and labeling bottles. Technicians refer any questions regarding prescriptions, drug information, or health matters to a pharmacist.

Pharmacy aides help licensed pharmacists with administrative duties in running a pharmacy. Aides often are clerks or cashiers who primarily answer telephones, handle money, stock shelves, and perform other clerical duties. They work closely with pharmacy technicians. Some also clean pharmacy equipment, help with the maintenance of equipment and supplies, and manage the cash register. To become a pharmacy aide, one should be able to perform repetitious work accurately. Because most of pharmacy personnel deal constantly with the public, they should be neat in appearance and deal pleasantly and tactfully with customers.
All pharmacists have the obligation to act in the best interest of the patient, observe the law uphold the dignity and honor of the profession. The pharmacist:

- establishes and maintains an unique relationship with each patient;
- promotes the well-being of every patient;
- preserve the confidentiality of information about individual patients (except in instances where there is a compelling need);
- act with honesty and integrity.

**Resources of medicine Information**

Information about medicines is the necessary and important component of the pharmaceutical providing. That`s why WHO determines medicine as "medicinal matter plus information about it". To achieve necessary pharmacotherapeutic effect both medical and pharmaceutical specialists and patients must have high-quality, complete and timely information about medicines which are used.

Therefore the basic users of pharmaceutical information are:

- pharmacists and druggists;
- doctors and other medical workers;
- leaders of different subsections of the health and pharmaceutical care system (companies, firms, enterprises and others like that);
- patients (population).

The type and volume of the information about medicines for these basic groups of users is different and depends on the whole row of factors and circumstances: profession, specialization, position, experience and others like that. The informative necessities of specialists (medical and pharmaceutical workers) divide into information of pharmacotherapeutic and pharmaceutical character.

The indication to application, methods of the use and dosage, contra-indications; mechanism of action; pharmacological properties; indirect action; repugnance with other medicines; pharmacodynamic indexes; pharmacokinetic data and others like that belong to information of **pharmacotherapeutic character**.
The composition and medicine form, term of fitness; terms of storage; stability; producer; price belong to information of pharmaceutical character.

For the leaders of health care and pharmaceutical system, organizations needs the information of more general character such as mainly regulation of legal relations of subjects at the pharmaceutical market.

For patients necessary information is about dosage of appointed medicines, rational methods of application, negative medicine action and possible ways of its prevention, possible incompatibility, correct medicine storage, possibility of replacement by other medicine.

Information resources are divided into official and unofficial. To the official sources belong: State Register, State pharmacopoeia, normative documents in relation to creation, production, quality control and the medicine realization, instruction about the medicine application, informative etc.

Unofficial information generators are divided into primary and second. Primary original /sources/ are protocols of results of the preclinical and clinical tests, protocols of the medicine analyses on all stages of their motion, hospital chart, reports about scientific work, scientific articles where the first results of researches are presented.

The second sources are the result of generalization, standardization and reduction of primary documents. The literary reviews on problems of pharmacotherapy, encyclopaedias, reference books, textbooks and others the scientific articles like that belong to this type of sources.

To this group of information belongs databases access to which is provided by phone, fax, on diskettes, compact disks, in the Internet. For example, the database of “Toxline” (THE USA) contains information about the grant of Medicare at poisonings, the database of PDQ gives recommendations about modern chemicaltherapeutic facilities for treatment of malignant new formations. The specialists of health care must know about these information generators and have an access to them.
Official information generators about medicines

State medicine register of Ukraine is unique official record which includes information about medicines which are settled to application in medical practice in the moment of its output, it is the most essential informative document at the pharmaceutical market, so as contains information about all incorporated in a country ready medicines, substances, medical vegetable raw material and auxiliary matters which are used for production of medicines. It is periodically looked over. Thus the out-of-date, small effective medicines and those, in the process of application of which the exposed undesirable action are eliminated from it.

In the State register of Ukraine is marked: auction name, producer, INN, synonyms, chemical name or composition, pharmacological action, pharmacotherapeutic group, testimony, contra-indication, measures of suppression, co-operation with other medicines, methods of application and doses, indirect action, forms of issue, terms of storage and other.

Forming of the State register carries out by the State Pharmacological center of Health care Ministry of Ukraine.

State Pharmacopoeia of Ukraine is a basic normative document from the control of the medicine quality. Its requirements are obligatory for all enterprises and establishments of Ukraine which produce, keep, control and will realize medicines, regardless of pattern of ownership.

In the State Pharmacopoeia of Ukraine structure – 101 general and 100 separate articles (monographs).

It is fully harmonized with the European pharmacopoeia, and also is contained the national requirements. How the official SPhU information generator necessary foremost to the specialists, which are engaged in the medicines creation, their production, and also the control of quality is carried out on all stages of their life cycle.

Information about the medicine application also is official. This information is given in three prospects:
1. Instruction about medical application is information for a doctor;
2. It is information for a patient;
3. Information, that is inflicted on packing (the medicine label).

All three types of information are official.

Instruction about medical application contains maximally complete information at medicines:

1. The medicine Name taking into account all its features;
2. General description with exposition of the basic properties;
3. Composition of medicinal preparation and form of issue;
4. Pharmacological properties with illumination of pharmacodynamics and pharmacokinetics;
5. Testimony to application;
6. Method of application and dose;
7. Indirect action;
8. Contra-indication;
9. Overdosing;
10. Features of application;
11. Co-operation with other medicines;
12. Terms of storage;
13. Terms of vacation from pharmacies;
14. Packing;
15. Name and address of producer.

In information for a patient complete information medicine is pointed, instruction to which must be concluded in accordance with the medicine description and laid out in an accessible form for an user which applies medicine independently. It is to contain, at least, the list of information: medicine name, complete description of operating and auxiliary matters with pointing of their amount, pharmacotherapeutic group or type of action, name of declarant and/or producer,
testimony to application and information which is needed for the correct application: contra-indication, warning at application, co-operation with other medicine and food products, dose, method and multiple of introduction, duration of treatment, measures at overdosing etc.

THE ORGANIZATION OF WORK OF PRESCRIPTION DEPARTMENT IN PHARMACY. RULES OF EXCERPTION AND RECEPTION OF RECIPES

A prescription department is the department for reception of prescriptions and delivery of drugs. At this department medicines are made and sold according to prescriptions. There one may buy powders and pills, mixtures and ointment, tinctures and decoctions as well as drops, suppositories etc.

Prescription department is a major structural unit of the pharmacy. It performs the following functions:

- Production;
- Trade;
- Informative.

To perform its functions prescription department executes the following subfunctions:

- Receives prescriptions from out-patients and the requirements from the hospitals to produce extemporeus drugs;
- The compounding, quality control, dispensing on prescription drugs and other medical assortment;
- Carrying out laboratory-filling operations (preparation of the concentrates, intermediate products and packaging of drugs).

Staff of the department. Head of the department and his deputy carries out management of the department. According to the staffing situation in the department work pharmacists, pharmacist-analyst.

Prescription department apartments, equipment of workplace of pharmacist. The nomenclature of the premises depends on the specific production of pharmacy.
Pharmacy with the right of production of non-sterile drugs should have the production facilities: assistant room, the pharmacist-analyst room or table, room for purified water, for sterilization of pharmaceutical ware.

If the pharmacy has the right to manufacture drugs under aseptic conditions, it should also have the aseptic block, sterilization room, facilities for obtaining water for injection and control labeling and hermetic packaging of medicine, room for pharmacist-analyst.

**Duties of the pharmacist on receiving of the recipes:**

- Receiving prescriptions and requirements from the hospitals, checking the correctness of their design, compatibility of ingredients in the recipe, compliance of prescribed doses to the patient's age, determination of the cost of drugs;
- Accounting of received prescriptions and send them to compounding;
- Informing the head about a violation of the rules of prescribing by physicians, the lack of necessary medicines in the department;
  - Pharmaceutical care;
  - Provision of first aid;
  - Providing information to visitors about the possibility of purchasing drugs in other drug stores (in the absence of drugs).

*The pharmacist has the right to:*

- Provide information to doctors about drugs (use, dosage, possible to replace in case of temporary absence, etc.);
- Check the correctness of storage, recording and dispensing drugs in health facilities offices (on behalf of the head of the pharmacy).

Workplace of the pharmacist is equipped with tables, cabinets for storage of finished drugs, refrigerator, closet for storage of controlled drugs, a cupboard with two swivel sections with built-in rotations.
In the work a pharmacist uses State Pharmacopoeia, reference books (on the application of drugs; on incompatibility of drugs), the table with higher single and daily doses of drops, separate orders Ministry of Health, which regulate the rules of prescribing and dispensing of drugs, the price list of the drugs, record books (for registration of received prescriptions; journals to record prescriptions), reference sheet, where the designation of pharmacies where you can buy drugs, temporarily absent in the pharmacy is given, as well as office equipment (a set of stamps, calculator). Pharmacies are also used computer equipment, which allows quickly realize the medicines.

Figure. **Responsibility of a pharmacist for violating the established rules of drug realization**

**RECIPE, ITS MAIN FUNCTIONS.**

An encyclopedic determination of "recipe" means that it is the writing address of doctor to the druggist about making and delivery of medicine with pointing of method their application. In addition, a recipe is a legal document, for violation of rules of work with which foreseen administrative and on occasion even criminal responsibility.
The order of excerption of recipes and remedies realization from pharmacies is regulated, by the basic orders of Ministry of health protection of Ukraine.

*Functions of recipe (scheme 5):*

**Medical** – recipe is a document allowed medicines dispensing and using by patients in accordance to the doctor administrations about dosage and addition order, talking into account the individual characteristics of patient.

**Juridical** - is defined by date of prescription, patient’s and doctor’s surname availability, using of appropriate recipes blanks, talking into account pharmacological drug properties. Persons who have prescribed the recipe and have prepared medicines in accordance to it have a legal liability.

**Manufacture (technological)** - is a pharmacist’s guideline to drugs manufacture showing ingredients should be taken and medicinal form should by created.

**Economical** - recipe is a document for expenditure of medicinal and auxiliary substances, tariff’s liquidation and accounts (in case of free or discount medicines).

**Social** - recipe must guarantee qualified and valuable pharmaceutical aiding for citizens of any social-economical status.
Structure of recipe

The word *prescription* is derived from the Latin word *prescriptio* (pre-“before”, scribo – “I write”). It may be defined as the formula which a physician writes, specifying the substances he intends to have administered to a patient.

The Latin language is preferred here in writing prescription as it is also in many countries. The advantages of the use of Latin is designating the ingredients of the prescription are obvious:

1. It is the languages of science and is understood to a greater or less extend throughout the civilized world.
2. It is the dead language and therefore not subject to the changes that are common to all living form of speech.
3. The Latin names for medicines are distinctive and very nearly the same in all countries.
4. It is frequently necessary and always advisable to withhold from a patient the names and properties of the medical agents administered. This can be usually effected by the use of the Latin technical terms.

The parts of prescription.

1. **Inscriptio** – in this part of prescription name, address and phone number of health protection establishment is indicated.
2. **Datum** – date of excerptio of recipe.
3. **Nomen aegroti** – the name of the patient. It should be placed at the top of the prescription be the prescriber and should be transferred to the lable by the
compounder. Serious accidents have sometimes occurred through neglect of this direction as when an adult dose of a medicine has been given to a child, owing to the similarity of the appearance of an adult’s medicine and that of a child and the name of the patient not appearing on either label.

4. **Nomen medici** – the name and initial of the physician – the name of prescriber is rarely sight in full, particularly since the very general use of printed prescription blank which contain not only the full name of the physician but also his office address. It is necessary sometimes to communicate quickly with the physician in case error or ambiquity and when printed blanks are not use, the name and address of the prescriber should be written in full.

5. **Invocatio** – superscription or heading – this invariably consist, in Latin prescription, of the symbol R, which is an abbreviation of the word recipe (“take”), the imperative of the Latin word *recipio*.

6. **Designatio materiarum** or **Orginatio** – the inscription or name and quantities of the ingredients – this part of the prescription is undoubtedly the most important of all and requires the greatest amount of care. The official title of the ingredient should always be used for designating those which are official.

A model prescription, if it is of the compound class, is presumed the following:

- The basis or chief active ingredient;
- The adjuvant or aid to the basis, to assist its action;
- The corrective which is intended to quality the action of the basis and adjuvant.
- The vehicle, the ingredient which serves to “carry all”, or hold them together, dilute them, and give to the whole the proper consistence, form and color. This is sometimes called the diluent.

The ingredients are occasionally written down by the physician in the order given above but this rule is frequently deviated from and they follow in the order of their importance. This is a matter of a small moment to the pharmacist, however, for he always has to consider solubility, compatibility
and other necessary considerations which determine the order if the prescription is to be compounded properly.

7. **Praescriptio or Subscriptio** – the subscription or the direction to the compounder – in the vast majority of prescription the subscription is contracted to a single letter or word, as M. or Misce, fiat etc. the physicians relies upon the skill of the pharmacist and generally gives no specific directions.

8. **Signatura** – the signa (mark) or the direction to the patient - it is usually abbreviated S. formally these directions are written in Latin but it is rarely the case now. There is, indeed, no good reason for writing them in Latin. The direction should be known to the patient and should be written in the vernacular on the label in a clear, distinct hand. The careless habit of not specifying the direction, by writing “as directed” of “use as directed” is greatly to be deprecated. Frequently the patient forgets the verbal directions or misunderstands them and even if he members at the time the directions may soon forget them and afterwards take a double dose by mistake. That’s why the directions for the patient should be written in full, explicitly and in plain languages.

9. **Subscriptio medici** – the signature and the stamp of the practitioner are the last part if the prescription.

**Common rules of excerption of recipes**

Doctors of medical establishments, including clinics, research institutes, medical educational establishments, legal and physical entities, which are engaged in medical practice are to write to the patient’s recipes on medications notarized by the signature and personal seal. Dental doctors, accoucheurs can write to the patients recipes on medications necessary for the grant of urgent medical aid, except for narcotic and psychotropic, specifying the medical position, notarizing a recipe by the signature and seal of establishment of health protection.

Recipes must be written by Latin with pointing of patient age (for paediatric patients, date of birth and weight must also be entered), order of payment, form of
application. It must be printed in a printing-house according to forms, ratified by Ministry of health protection (MHP in short). Doctors write recipes, as a rule, after examination of patient and at an obligatory record of this medications or goods of the medical setting in a medical document (medical card, for example).

It is forbidden to write recipes on medications which not settled to medical application in Ukraine. Nevertheless constantly in State Register of remedies is made alterations by the proper orders of MHP that is conditioned in a number of reasons:

- by the appearing of new remedies on the pharmaceutical market of Ukraine and there registration;
- by the withdrawal for diverse reasons of some medicine from the State register;
- by the necessity of re-registering in every five years, etc.

Recipes must be written expressly and legibly, by inks or ball-point pen with the obligatory filling of all necessary essential elements in a form. Corrections in a recipe are not settled. As for today it’s legally only hand-written excerption of recipe. Another ways of excerption, in particular computer, with the help stamp-clinics etc., not so far legalized.

It is possible to use only acceptable Latin abbreviations for prescribing recipes (table 5).

Table 5

<table>
<thead>
<tr>
<th>Abbreviations in Latin</th>
<th>Full name</th>
<th>Translation</th>
</tr>
</thead>
<tbody>
<tr>
<td>aa</td>
<td>ana</td>
<td>equally, of each</td>
</tr>
<tr>
<td>ac., acid.</td>
<td>acidum</td>
<td>acid</td>
</tr>
<tr>
<td>amp.</td>
<td>ampulla</td>
<td>ampoule</td>
</tr>
<tr>
<td>aq.</td>
<td>aqua</td>
<td>water</td>
</tr>
<tr>
<td>aq. pur.</td>
<td>aqua purificata</td>
<td>purified water</td>
</tr>
<tr>
<td>but.</td>
<td>butyrum</td>
<td>butter</td>
</tr>
<tr>
<td>comp., cps., cp.</td>
<td>compositus (a, um)</td>
<td>compound</td>
</tr>
<tr>
<td>D.</td>
<td>Da, Detur, Dentur</td>
<td>to give out</td>
</tr>
<tr>
<td>D. S.</td>
<td>Da. Signa, Detur. Signetur</td>
<td>to give out, to administer</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Latin Term</td>
<td>Description</td>
</tr>
<tr>
<td>--------------</td>
<td>------------</td>
<td>-------------</td>
</tr>
<tr>
<td>D. t. d.</td>
<td>Da (Dentur) tales doses</td>
<td>to give out such doses</td>
</tr>
<tr>
<td>dil.</td>
<td>dilutus</td>
<td>dissolved</td>
</tr>
<tr>
<td>div. in p. aeq.</td>
<td>divide in partes aequales</td>
<td>divide in equal parts</td>
</tr>
<tr>
<td>extr.</td>
<td>extractum</td>
<td>extract</td>
</tr>
<tr>
<td>f.</td>
<td>fiat(fiant)</td>
<td>let form</td>
</tr>
<tr>
<td>gtt.</td>
<td>gutta, guttae</td>
<td>drop</td>
</tr>
<tr>
<td>inf.</td>
<td>infusum</td>
<td>infusion</td>
</tr>
<tr>
<td>in ampull.</td>
<td>in ampullis</td>
<td>in ampoules</td>
</tr>
<tr>
<td>in tab.</td>
<td>in tabulettis</td>
<td>in tablets</td>
</tr>
<tr>
<td>lin.</td>
<td>linimentum</td>
<td>liniment</td>
</tr>
<tr>
<td>liq.</td>
<td>liquor</td>
<td>liquid, solution</td>
</tr>
<tr>
<td>M. pil.</td>
<td>massa pilularum</td>
<td>pill’s masse</td>
</tr>
<tr>
<td>M.</td>
<td>Misce, Misceatur Misce, Misceatur</td>
<td>to mix</td>
</tr>
<tr>
<td>N.</td>
<td>numero</td>
<td>number</td>
</tr>
<tr>
<td>ol.</td>
<td>oleum</td>
<td>oil</td>
</tr>
<tr>
<td>pil.</td>
<td>pilula</td>
<td>pill</td>
</tr>
<tr>
<td>p. aeq.</td>
<td>partes aequales</td>
<td>equal parts</td>
</tr>
<tr>
<td>pulv.</td>
<td>pulvis</td>
<td>powder</td>
</tr>
<tr>
<td>q. s.</td>
<td>quantum satis</td>
<td>of sufficient quantity</td>
</tr>
<tr>
<td>r., rad.</td>
<td>radix</td>
<td>root</td>
</tr>
<tr>
<td>Rp.</td>
<td>Recipe</td>
<td>to take</td>
</tr>
<tr>
<td>Rep.</td>
<td>Repete, Repetatur, Repete, Repetatur</td>
<td>repeat</td>
</tr>
<tr>
<td>rhiz.</td>
<td>rhizoma</td>
<td>rhizome</td>
</tr>
<tr>
<td>S.</td>
<td>Signa, Signetur</td>
<td>to administer</td>
</tr>
<tr>
<td>sem.</td>
<td>semen</td>
<td>seed</td>
</tr>
<tr>
<td>simpl.</td>
<td>simplex</td>
<td>simple</td>
</tr>
<tr>
<td>sir.</td>
<td>sirupus</td>
<td>syrup</td>
</tr>
<tr>
<td>sol.</td>
<td>solutio</td>
<td>solution</td>
</tr>
<tr>
<td>supp.</td>
<td>suppositorium</td>
<td>suppository</td>
</tr>
<tr>
<td>tab.</td>
<td>tabuletta</td>
<td>tablet</td>
</tr>
<tr>
<td>t-ra., tinct., tct</td>
<td>tinctura</td>
<td>tincture</td>
</tr>
<tr>
<td>unq.</td>
<td>unquentum</td>
<td>ointment</td>
</tr>
<tr>
<td>vitr.</td>
<td>vitrum</td>
<td>glass</td>
</tr>
<tr>
<td>ppt., praec.</td>
<td>praecipitatus</td>
<td>precipitated</td>
</tr>
</tbody>
</table>
The dose required must not be expressed in terms of the dosage form for single ingredient preparations e.g. "ATENOLOL 2 tablets" is not acceptable. It should be written as "ATENOLOL 100mg".

Route of administration (way of using). Only the following abbreviations are acceptable in some countries of the world (table 6). Other routes of administration must be written in full (eg. via nasogastric tube). It is safer if only one route of administration is specified for each medicine. Where two routes must be specified eg. O/IV this is only allowed if both the dose and frequency are the same for each route. For "As required" medicines the times for administration must be written by the prescriber, using the 24-hour clock in the relevant section of the prescription document. A maximum dose in 24 hours must be stated.

Table 6

<table>
<thead>
<tr>
<th>Acceptable abbreviations</th>
<th>Meaning</th>
<th>Acceptable abbreviations</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>I.M.</td>
<td>for intramuscular</td>
<td>P.R.</td>
<td>for rectal</td>
</tr>
<tr>
<td>INHAL</td>
<td>for inhalation</td>
<td>P.V.</td>
<td>for vaginal</td>
</tr>
<tr>
<td>I.V.</td>
<td>for intravenous</td>
<td>S.C.</td>
<td>for subcutaneous</td>
</tr>
<tr>
<td>NEB</td>
<td>for nebulised</td>
<td>SUBLING</td>
<td>for sublingual</td>
</tr>
<tr>
<td>O.</td>
<td>for oral</td>
<td>TOP</td>
<td>for topical</td>
</tr>
</tbody>
</table>

For certain medications, it may not be easy to define a maximum 24 hour dose (eg. for nebulised salbutamol, glyceryl trinitrate). In these situations the frequency of dosing must be prescribed but the time may be determined locally, in accordance with an agreed protocol or procedure. Premedication (before surgical procedures) should be prescribed by using the "once only" section.

For controlled drugs, the prescriber's full signature is always necessary. The signature of a medical student is not acceptable. In the interests of patient safety and risk management, verbal instructions for the administration of a medicine must not be given or accepted over the telephone.
Prescriptions for controlled drugs for out-patients or patients on discharge must be:

- Handwritten by the prescriber in indelible ink.
- Signed and dated by the prescriber.
- Complete in all respects and state:
  - the name and home address of the patient.
  - the total quantity of the medicine in both words and figures.
  - the form and strength of the medicines.
  - the dose.

Return of controlled drugs

Controlled drugs, when no longer required, should be returned to pharmacy by the ward pharmacist. Ward pharmacists should witness the destruction of small amounts of expired stock at ward level. The destruction of any quantity of controlled drugs (however small) must be undertaken in the presence of a witness and the destruction recorded.

Order of excerption of recipes on two types of form

For excerption of recipes two types of forms are foreseen in Ukraine (Form 1 & Form 3).

Form №1

For excerption named medicinal forms:

1. Medicines of general list for an overall cost.

   Essential elements: doctor’s signature and personal seal.

2. Quantity controlled medicines:
   - Narcotic, dopey and psychotropic medications, precursors in a mixture with the non-indifferent matters.
     - Codeine phosphate
     - Ethylmorphine hydrochloride
     - Phenobarbital

By Law the pharmacist is not permitted to dispense prescriptions for controlled drugs, unless all the above information is detailed on the prescription.
Sodium phenobarbital
Barbamyle
Ephedrine hydrochloride etc.

- Poison medications, strong medicines (table 7)
- Others groups of medicines

Table 7

<table>
<thead>
<tr>
<th>Poison medications</th>
<th>Strong medicines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atropine sulfate</td>
<td>Dimedrole</td>
</tr>
<tr>
<td>Ketamine</td>
<td>Butorphanol</td>
</tr>
<tr>
<td>Tetracaine</td>
<td>Zopiclone</td>
</tr>
<tr>
<td>Tramadol</td>
<td>Clonidine</td>
</tr>
<tr>
<td>Trihexiphenidyle</td>
<td>Metandienone</td>
</tr>
<tr>
<td>Muscul relaxants:</td>
<td>Nandrolon</td>
</tr>
<tr>
<td>Atracurium, Vecuronium, Mivacurium, Pancuronium, Pipecuronium, Rocuronium, Suxamethonium, Tubocurariaium, Cisatracurium</td>
<td></td>
</tr>
</tbody>
</table>

**Essential elements:** doctor’s signature and personal seal + seal of health protection establishment.

3. Medications free of charge or on favorable terms.

**Essential elements:** doctor’s signature and personal seal + seal of health protection establishment.

A. Period of validity: 1 month.
B. Period of storage: it. 1. – is not stored into pharmacy
   it. 2. – 1 year,
   it. 3. -3 years

**Form №3**

For excerption of narcotic and psychotropic medications and preursors in a pure form or in a mixture with the indifferent matters (distil water, sugar, medicinal starch etc.)
**Essential elements:** doctor’s signature and personal seal + seal of health protection establishment + leader’s of health protection establishment signature.

A. **Period of validity:** 5 days.
B. **Period of storage:** 5 years

Composition of medication, determination of technological form of medicine, address of doctor to the pharmacist about making and delivery of medications is written with Latin. The use of Latin reductions is here settled only accordingly accepted in medical and pharmaceutical practice and MHP ratified by the orders.

The names of narcotic medications, psychotropic and poisonous matters are written at the beginning of recipe, and all other medical and auxiliary matters are farther.

On the form № 3 it is settled to write one name of medication only, on the form of form №1, is not greater three names (only for medicines of general list for an overall cost!).

The method of medicine application is written with an official language (or other languages according to Law of Ukraine "About languages in Ukraine") with pointing of dose, frequency (periodicity) of application, time of reception (to or after food) and duration of course of treatment. It is forbidden to be limited to the common pointing of type "External", "Internal", it is "Known", etc.

At a necessity immediate vacation to the patient of medicine the mark of "cito" is filled in overhead part of recipe - quickly or "statim" - immediate.

Amount of rare medications excerption of recipes is specified in milliliters or drops, all other - in grammas.

For medications which have set by the orders of MHP maximum norm of vacation on one recipe, it is not settled to write in a recipe the indicated medications in a greater amount, than the set norm.

In the case of necessity it is settled to write in a recipe medications in amounts, which is needed for continuation or reiteration of course treatment, except for medications which the norms of vacation are set for. On a recipe here a doctor does
the proper record: "On the course of treatment", that is additionally notarized by his signature and personal seal.

At excerption to the chronic patients of recipes on medications it is settled to set the term of action of recipe in the scopes of to one year, after the exception:

a) remedies which are subject to the in quantitative account (an in quantitative account has for a purpose to fix after every name technological form information about all operations on the receipt and realization);

б) remedies which are released free of charge and on favorable terms;

в) steroids, medications which contain the poisonous matters (except for those, which are used for treatment of glaucoma and cataract).

At excerption of such recipes a doctor is under an obligation to do pointing "chronically patient" to specify the term of action of recipe and periodicity of vacation of medicine (every week, monthly, etc.), notarize it by the signature and personal seal.

It is settled to write medications to the separate categories of patients (which have diabetes, bronchial asthma, oncologic, hematological diseases, tuberculosis, heavy diseases of skin and others) if necessary (business trip, vacation, etc.) in the amount foreseen for the two-month course of treatment, taking into account the norms of vacation of medications, including and alcohol of ethyl on one recipe.

On poison, dopey, narcotic and psychotropic medications and alcohol ethyl the requirements are written individually from the requirements on other medications. Such requirements are notarized accordingly by the seal of establishment of health protection.

In the requirements necessarily there must be the name of separation (cabinet), dosage of medications, concentration of ethyl alcohol, and also setting of medication.

Recipes for the receipt of medications free of charge or on favourable terms it is settled to write to the doctors of state establishments of health protection, doctors of other enterprises, organizations which have the proper facilities on payment of
recipes, the list of which is determined by the organs of health protection of local state administrations.

Narcotic, psychotropic medications and prekursors it is settled to write only to the doctors which work in state and communal establishments of health protection.

Recipes are written in one copy. In the case of excerption of narcotic or psychotropic medications free of charge or on the favorable terms there must be written out recipe on the form № 3 and recipe on the form № 1 written additionally.

It is settled to write recipes on eyes drops and other preparations with short space of storage, which are used during a long period, to the separate categories of patients, what the foreseen free or favorable vacation, in an amount necessary for conducting of treatment during one month, except for narcotic and psychotropic medications, steroids and medications which have dopey action.

A recipe, which is written out with violation of requirements of rules or is contained incompatible remedies, is considered invalid, and medicine after such recipe can’t be realized. Such recipe is paid off by the stamp "Recipe invalid" and is come back to the patient.

Doctors and other medical practitioners who write recipes carry responsibility in accordance with established procedure for setting to the patient of medicine and observance of rules of excerption of recipes.

**Organisation of vacation of medications in majority of countries**

The prescription is received and read by the pharmacist on the reception of recopes and he learns whether the customer will wait or come later. Usually these facts are written upon a blank form which is clipped to the prescription when it is turned over for filling. The coupon which carries a call number is handed to the waiting customer to identify the prescription when filled. The prescription should be read over carefully, and judgment mentally pronounced, first upon the safety of the doses of the respective ingredients, and then upon their compatibility.

1. The prescription is received.
2. The clock number is stamped in duplicate on the blank and on the coupon, and, it is a call package, the coupon is then detached and handed to the waiting customer.

3. The label is now written, using the prescription number and the clock number is also stamped on the label.

4. All facts are now recorded in a book ruled for the purpose, as follows:

<table>
<thead>
<tr>
<th>clock number</th>
<th>Doctor</th>
<th>Patient</th>
<th>Article</th>
<th>Clerk</th>
</tr>
</thead>
<tbody>
<tr>
<td>002483</td>
<td>Brown</td>
<td>Jones</td>
<td>4684</td>
<td>signature</td>
</tr>
</tbody>
</table>

5. The compounding clerk then takes the prescription, label, etc., signs his name in the book, fills the prescription and stamps his name on the blank.

6. The dispensing clerk completes the prescription by attaching the label and checking all details of the prescription with another clerk, the latter also placing his name on the blank.

7. The dispensing clerk now wraps the package and hands it out for delivery.

Sometimes pharmacist uses no checks or numbered coupon but prefers to use the name of the customer for the identification of the filled prescription. The order blank suggests for the identification of the filled prescription.

It is universal practice to number the prescriptions and to place a corresponding number upon the label, the object being to identify the bottle or package in case of renewal and connect it with the original prescription.

**Free of charge and privileged realization of drugs in Ukraine**

Dispensing of drugs free or on preferential terms prescribed by doctors can be done from pharmacies and pharmacy items. Payment for drugs dispensed on the basis of these prescriptions, carried out by local authorities or public health agencies on the basis of consolidated inventories, the second copy of the register along with the recipes is in a drugstore or pharmacy with the centralized accounting.

By the Resolution of the Cabinet of Ministers № 1303 from 17.08.1998, the "On the Regulation of free and favorable realization of prescription drugs...” have been approved:
- A list of categories of people eligible for benefits;
- A list of diseases for which outpatient drugs are provided free of charge.

Thus, the favorable realization (50% payment for the drugs) provides for the following categories of citizens:

- Disabled I-II group affected by the industrial injury, occupational or general disease;
- Disabled children groups I and II;
- Children aged from 3 to 6 years;
- Citizens, rehabilitated in accordance with the Law "On Rehabilitation of Victims of Political Repression in Ukraine," who were disabled as a result of reprisals or are pensioners;
- Persons awarded "Honorary donor Ukraine", "Honorary Donor of the USSR," according to the Law of Ukraine "On the donation of blood and blood components."

The following persons have a rights to receive drugs free:

- Citizens, for whom it is provided by the Law "On Status of Veterans, Guarantees of their Social Protection";
- Persons with special employment services to his country, whose interests are protected by the Law "On the main provisions of the soc. protection of labor veterans and other elderly citizens in Ukraine";
- Those who affected by the Chernobyl disaster;
- Children under the age of 3 years;
- Disabled children under the age of 16 years;
- Adolescent girls and women with contraindications pregnancy, women are affected by the Chernobyl disaster, provided free of contraception according to the National Program for Family Planning;
- Pensioners who receive the minimum pension, and persons with low income due to disability or loss of a breadwinner.

To diseases for which drugs are released for free, include: cancer, hematological diseases, diabetes, rheumatism, rheumatoid arthritis, edema, acute
systemic lupus, asthma, systemic, chronic, serious skin diseases, syphilis, leprosy, tuberculosis, Addison's disease, hepatolenticular disease, phenylketonuria, schizophrenia, epilepsy, dysentery, pituitary dwarfism, a condition after transplantation of organs and tissues, ankylosing spondylitis, myasthenia gravis, myopathy, Parkinson's disease, myocardial infarction (the first 6 months), AIDS, HIV infection, postoperative hypothyroidism, hypoparathyroidism, congenital dysfunction of the adrenal cortex, etc.

**ORGANIZATION OF WORK OF READY-MADE DRUGS DEPARTMENT. NON-PRESCRIPTION DRUGS DEPARTMENT. OTC-DRUGS REALIZATION.**

In *ready-made drugs department* the ready-made drugs are sold under the prescriptions.

List of functions of ready-made drugs department includes: trading function - realization of medicines on recipes; informative function - organization of sanitary-informative activity among the population, pharmaceutical care and informative aid to the hospitals on pharmaceutical questions; social function providing of the first medical aid and the aid for the privilege category of population.

One from the personnel of ready-made drugs department is pharmacist on the reception of recipes and realization of ready-made drugs. He has such duties as:

- Receiving prescriptions, checking the correctness of their design, compliance of prescribed doses to the patient's age;
- Accounting of received;
- Informing the head about a violation of the rules of prescribing by physicians, the lack of necessary medicines in the department;
- Pharmaceutical care;
- Provision of first aid;
- Providing information to visitors about the possibility of purchasing drugs in other drug stores (in the absence of drugs).

In the work a pharmacist uses separate orders Ministry of Health, which regulate the rules of prescribing and dispensing of drugs, the price list of the drugs, record books (for registration of received prescriptions; journals to record prescriptions), reference sheet, where the designation of pharmacies where you can buy drugs, temporarily absent in the pharmacy is given, as well as office equipment (a set of stamps, calculator). Pharmacies are also used computer equipment, which allows quickly realize the medicines.

**Organization of the non-prescription drugs department.** Main task of non-prescription department is the provision of timely and skilled pharmaceutical care. Department carries out trade and informative functions, sells drugs, which are allowed to realize without a doctor's prescription, as well as surgical dressings, medical devices, sanitation and hygiene, skin care products.

Non-prescription department is located in the hall of public services. It is equipped with a counter display cases, where goods and promotional items are located that distinguish this department of the ready-made drugs department, in which advertising is prohibited. Drugs are placed on display depending of pharmacotherapeutic groups (cardiovascular, vitamins, analgesics and antipyretics, etc.), and separately placed bandages, cosmetics, health and hygiene goods, medicinal plant.

The current stock of goods located in cabinets with drawers, on shelves. Goods placed in the windows must have a price list, designed properly. Leads the department a head and his deputy, in the department pharmaceutics and pharmacists are working.

Main duties and rights of the pharmacist are presented in the table.
List of main duties and rights of the pharmacist on realization of the non-prescription medicines.

<table>
<thead>
<tr>
<th>Duties</th>
<th>Rights</th>
</tr>
</thead>
<tbody>
<tr>
<td>To give full information on OTC drugs (particularly application, possible complications, medications and food interactions, etc.)</td>
<td>To replace the product in the OTC range</td>
</tr>
<tr>
<td>To check availability of an information sheet (annotation), shelf life, integrity of packaging of the drug</td>
<td>To require personal medical card</td>
</tr>
<tr>
<td>At the request of the client to give a more in-depth product information</td>
<td>To check solvency of the buyer if he pays with a credit card</td>
</tr>
<tr>
<td>Specify the rational use and storage conditions of drug</td>
<td></td>
</tr>
<tr>
<td>To provide brochures, pamphlets, leaflets, which are distributed among consumers</td>
<td>To recommend visiting a specialty physician (general practitioner, gynecologist, surgeon, etc.)</td>
</tr>
<tr>
<td>To give a sales receipt</td>
<td></td>
</tr>
</tbody>
</table>

Additional duties of employees of the non-prescription department:

1. Systematically replenish the supply of commodities and materials necessary to support the assortment*.
2. Ensure proper storage of goods.
3. Provide the realization of goods to buyers, explaining features and rules of admission drugs, store them at home.
4. Keep an accounting of the movement of inventories in the department.
5. Monitor the compliance with the sanitary regime in the department.

* In accordance with the applicable legislation pharmacies are required to maintain minimum assortment of goods

Total quantity of non-prescription drugs on domestic pharmaceutical market create non-prescription medicines market. Non-prescription medicines market as usually has the following levels (Fig.):
Over-the-counter (OTC) drugs are medicines that may be sold directly to a consumer without a prescription from a healthcare professional, as compared to prescription drugs, which may be sold only to consumers possessing a valid prescription. In many countries, OTC drugs are selected by a regulatory agency to ensure that they are ingredients that are safe and effective when used without a physician's care. OTC drugs are usually regulated by active pharmaceutical ingredients (APIs), not final products. By regulating APIs instead of specific drug formulations, governments allow manufacturers freedom to formulate ingredients, or combinations of ingredients, into proprietary mixtures.

The term over-the-counter may be somewhat counter-intuitive, since, in many countries, these drugs are often located on the shelves of stores like any other packaged product. In contrast, prescription drugs are almost always passed over a counter from the pharmacist to the customer. Some drugs may be legally classified as over-the-counter (i.e., no prescription is required), but may only be dispensed by a pharmacy employee after an assessment of the patient's needs and/or the provision of

Figure **Levels of non-prescription-medicines**

Manufactures

Regional representatives of manufactures

Distributors

Doctor

Pharmacist

Consumer

Registration of medicine and permission to non-prescription dispensing
patient education. In many countries, a number of OTC drugs are available in establishments without a pharmacy, such as general stores, supermarkets, gas stations, etc. Regulations detailing the establishments where drugs may be sold, who is authorized to dispense them, and whether a prescription is required vary considerably from country to country.

In various countries the requirements for OTC drugs are different. But among them there is a common pharmacotherapeutic, economic, consumer and information requirements (see Figure).

**Figure Requirements for OTC drugs**

**Pharmacotherapeutic:**
- drug or its ingredients have not direct or indirect harm (side effects, habituation)
- should be used only outpatient
- does not contain any substances, activity or side effects that require further study

**Consumer:**
- well known in the market and is often used
- easy to use

**Economic:**
- available at a price

**Informative:**
- containing instructions written in plain language the consumer
- active ingredients should be labeled on package

**Order of OTC medicines realization in foreign practice.** Abroad dispensing of OTC medicines has place through pharmacies, distribution network (supermarkets, shops), the Internet.
A special place in the OTC market assigned to the consumer. He buys OTC drug on the basis of: personal motives and preferences; recommendations of pharmacist, advises of relatives, friends, advertising and media information, the price of the drug; quality of packaging, etc.

An important condition for the normal development of the OTC market is a good pricing, advertising and informational work of manufacturers and distributors.

A feature of OTC drugs is the fact that the responsibility for belong primarily to a consumer. At the same pharmacist (chemist) should provide all necessary information about the drug.

Realizing OTC drugs through pharmacy, pharmacist should give to the patient who going to provide self-medication following advices:

- Before taking or using the medicines, read the instruction leaflet
- Check the expiry date
- Store the medicines in a cool place protected from light and moisture.
- Keep out of reach of children
- Consult your doctor if the medicines are for the elderly, pregnant women or children
- Before purchasing a medicine, ask your pharmacist or other healthcare professional for advice
- Do not take the medicine for longer than the period indicated on the instruction leaflet

_Witches between prescription and OTC_

As a general rule, over-the-counter drugs have to be primarily used to treat a condition that does not require the direct supervision of a doctor and must be proven to be reasonably safe and well-tolerated. OTC drugs are usually also required to have little or no abuse potential, although in some areas drugs such as codeine are available OTC (usually in strictly limited formulations or requiring paperwork or identification to be submitted during purchase). One of the oldest OTC drugs is aspirin.
Over time, drugs that prove themselves safe and appropriate for self-treatment, may be switched from prescription to OTC. An example of this is diphenhydramine (Benadryl) which once required a prescription but now is available OTC nearly everywhere. Diphenhydramine is a deliriant, nevertheless, most recreational drug users find its effects uncomfortable rather than exciting. More recent examples are cimetidine and loratadine in the United States, and ibuprofen (Herron Blue/Nurofen) in Australia.

It is somewhat unusual for an OTC drug to be withdrawn from the market as a result of safety concerns, rather than market forces, though it does happen occasionally, phenylpropanolamine being one example.

OTC medicines can help treat or prevent symptoms from illness or other health problems, such as allergies. However, sometimes OTC medicines can cause unpleasant effects, which are also called adverse effects. These adverse effects include side effects, drug-drug interactions and food-drug interactions. It is best to be aware of the risks so you know how to avoid them.

Certain situations put you at higher risk for adverse effects. Because the possible adverse effects differ from one OTC drug to another, pharmacist must give full information about medicine and note that patient must carefully read the label of any OTC medicine to know what to expect.

As said early, medicines for self-medication are often called 'nonprescription' or 'over the counter' (OTC) and are available without a doctor's prescription through pharmacies. In some cases OTC products are also available in supermarkets and other outlets. Medicines that are available from doctors with a prescription are called prescription products (Rx products).

The term 'responsible self-medication' is often used to emphasize the appropriate use of OTC medicines by informed patients and consumers, with healthcare professional support where necessary. By contrast, the term 'self-prescription' is used for the inappropriate practice of using prescription products
without medical supervision. Self-prescription is an unfortunate feature of a number of developing countries where good healthcare systems are absent or weak.

*Self-medication* is the treatment of common health problems with medicines especially designed and labeled for use without medical supervision and approved as safe and effective for such use.

Self-medication means treating ourselves for temporary or minor health problems such as colds, heartburn, allergies and headaches. These problems can be treated with over-the-counter medicines that can be purchased without a doctor's prescription.

Many healthcare organizations have made important statements on self-care and self-medication. Some selected illustrations only are given here:

The World Health Organization (WHO): "It has become widely accepted that self-medication has an important place in the healthcare system. Recognition of the responsibility of individuals for their own health and awareness that professional care for minor ailments is often unnecessary has contributed to this view. Improvements in people's general knowledge, level of education and socioeconomic status in many countries form a reasonable basis for successful self-medication." (Guidelines for the Regulatory Assessment of Medicinal Products for use in Self-Medication. 2000).

The International Federation of Pharmacists (FIP): "Nowadays people are keen to accept more personal responsibility for their health status and to obtain as much sound information as possible in order to help them make appropriate decisions in health care...Pharmacists and the manufacturers of nonprescription medicines share the common goals of providing high quality service to the public and encouraging the responsible use of medicines." (Joint Statement by The International Pharmaceutical Federation and the World Self-Medication Industry, 1999).

The International Council of Nurses (ICN): "Self-medication is a key component of self-care that is particularly significant in an era of increasing chronic illness and well-informed health care consumers. Optimising responsible self-
medication is an important and underused resource for health and provides an opportunity for collaboration and consultation among consumers, nurses, pharmacists and physicians." (Joint Statement by the International Council of Nurses and the World Self-Medication Industry, 2003).

Responsible self-medication can:

- Help to prevent and treat symptoms and ailments that do not require a doctor;
- Reduce the pressure on medical services where health care personnel are insufficient;
- Increase the availability of health care to populations living in rural or remote areas;
- Enable patients to control their own chronic conditions.

These benefits translate into patient and consumer wellness and productivity, economic gain for employers, and cost savings to healthcare budgets through reduced medicine budget cost and reduced physician visits.

In most countries patients and consumers are able to have direct access to products for many conditions, such as: acne, allergic conjunctivitis, arthritic pain, caries prevention, colds, cold sores, constipation, cough, diarrhea, fever, flu prevention and treatment, hay fever, headache, indigestion/heartburn, insomnia, mild/moderate pain, minor cuts and bruises, mouth ulcers, nausea, sore throat, symptoms of PMS, topical bacterial infections and weight management.

The list of treatable conditions and available products continues to grow as the benefits of responsible self-medication are realized. Together with self—medication another term has place in pharmaceutical practice – self-care.

Self-care is a lifelong habit and culture. It is the action individuals take for themselves and their families to stay healthy and manage minor and chronic conditions, based on their knowledge and the information available, working in collaboration with healthcare professionals where necessary.

Self-care therefore includes many elements other than responsible self-medication, such as making healthy lifestyle choices or self-recognition, self-
monitoring and self-management of symptoms or disease, in partnership with healthcare professionals.

In reality, self-care is the foundation in the pyramid of healthcare. If an average healthy person visits a doctor say 9 times in a year, with a total of 1,5 hours of discussion, the remaining 8758.5 hours of the year are self-care.

**PHARMACEUTICAL CARE**

In the last quarter century, pharmacy has expanded its role within the health care delivery system from a profession focusing on preparation and dispensing of medications to patients to one in which pharmacists provide a range of patient-oriented services to maximize the medicine's effectiveness.

Is this the right medicine, doc?" In 1948, patients asked their pharmacists that question every day, and physicians didn't seem to mind at all. Fifty years later, patients don't refer to their pharmacists as "doc," but they still ask the same question. Now, however, physicians seem concerned about pharmacists intruding on their turf as providers of medical care and advice.

The worry comes as pharmacists seek an increased role in providing counseling and clinical services to patients as well as greater payment for their services. Pharmacists see themselves as health care professionals licensed to apply their special knowledge, and they're telling health care systems, patients and insurers that they are an integral part of the managed care solution or pharmaceutical care.

**Statement on Pharmaceutical Care**

*Pharmaceutical care* is the responsible provision of drug therapy for the purpose of achieving elimination or reduction of a patient's symptomatology; arresting or slowing of a disease process; or preventing a disease or symptomatology.

This process requires a pharmacist to review a patient's medication with reference to the doctor's diagnoses, laboratory tests and patient's information. The pharmacist must therefore work very closely with the doctor and patient in order to
gain a correct understanding of the relevance and impact of the various medications on the patient's pathology.

The pharmaceutical care process was originally conceived to be undertaken in a community pharmacy by community pharmacists. In New Zealand in 1996 the Pharmaceutical Society began a programme to implement the process. While some 500 pharmacists undertook an expensive training, it was found that the basic skill level of most pharmacists was not sufficient to enable them to undertake an in-depth review of the patients' medication [Citation Required]. Pharmacists are now required to complete a postgraduate diploma in pharmacy to enable them to practice as a Pharmacist before being considered competent to work at this level.

So, pharmaceutical care is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient’s quality of life. These outcomes are: cure of a disease, elimination or reduction of a patient’s symptomatology, arresting or slowing of a disease process, or preventing a disease or symptomatology.

Pharmaceutical care involves the process through which a pharmacist, in cooperation with a patient and other health professionals, designs, implements, and monitors a pharmaceutical care plan that will produce specific therapeutic outcomes for the patient. This in turn involves three major functions performed by the pharmacist: identifying potential and actual drug-related problems, resolving actual drug-related problems, and preventing potential drug-related problems.

Pharmaceutical care is a necessary element of health care that should be integrated with other elements. Pharmaceutical care is, however, provided for the direct benefit of the patient, and the pharmacist is responsible directly to the patient for the quality of that care. The fundamental relationship in pharmaceutical care is a mutually beneficial exchange in which the patient grants authority to the provider and the provider gives competence and commitment (accepts responsibility) to the patient.
The fundamental goals, processes, and relationships of pharmaceutical care exist regardless of practice settings.

- The basis of pharmaceutical care is responsibility and accountability to patients for the outcome of their drug therapy.
- The overall goal of pharmaceutical care is to maintain patients at the highest possible level of functional and psychosocial well-being through optimal management of drug therapy.
- Pharmaceutical care requires continuity of care between different practice settings.

**Drug-Related Problems**

Pharmaceutical care involves the pharmacist in three major functions on behalf of the patient: identifying potential and actual drug-related problems, resolving actual drug-related problems, and preventing potential drug-related problems. A drug-related problem is an event or situation involving drug therapy that actually or potentially interferes with an optimum outcome for a specific patient.

Drug-related problems include:

- Untreated indications. The patient has a medical problem that requires drug therapy but is not receiving a drug for that indication.
- Improper drug selection. The patient has a drug indication but is taking the wrong drug, or is taking a drug that is not the most appropriate for the special needs of the patient.
- Subtherapeutic dosage. The patient has a medical problem that is being treated with too little of the correct medication.
- Failure to receive medication. The patient has a medical problem that is the result of not receiving a medication due to economic, psychological, sociological, or pharmaceutical reasons.
- Overdosage. The patient has a medical problem that is being treated with too much of the correct medication.
- Adverse drug reactions. The patient has a medical problem that is the result of an adverse drug reaction or adverse effect.
- Drug interactions. The patient has a medical problem that is the result of a drug-drug, drug-food, or drug-laboratory test interaction.
- Drug use without indication. The patient is taking a medication for no medically valid indication.
- Treatment failures. The patient has a medical problem that is being treated with a medication that is generally considered appropriate for the indication, but the desired therapeutic outcome is not achieved.

Its main aim is to work in partnership both with other healthcare professionals and with patients, to ensure they make the best and safest use of medicines.

Pharmaceutical care reflects a systematic approach that makes sure that the patient gets the right medicines, in the right dose, at the right time and for the right reasons. It is about a patient-centred partnership approach with the team accepting responsibility for ensuring that the patient's medicines are as effective as possible and as safe as possible. This is done by identifying, resolving and preventing medicine-related problems so the patient understands and gets the desired therapeutic goal for each medical condition being treated.

Pharmacists can and do make a unique contribution to improving patient care. Medicines are the most common of all the steps taken by clinicians to help treat patients. And of all the healthcare professions, pharmacists have the widest knowledge in the science and use of medicines. Whether in the community, in local hospitals or specialist units, pharmacy focuses on empowering and protecting patients. Pharmacists have a key role to play in ensuring health gain wherever medicines are used.

Pharmacists provide care not just to patients but to the wider general public. The 'pharmaceutical health' of the nation depends on good access to medicines, advice and to tailoring therapy to the needs of individuals.

**Principles of Practice for Pharmaceutical Care**
Pharmaceutical Care is a patient-centered, outcomes oriented pharmacy practice that requires the pharmacist to work in concert with the patient and the patient's other healthcare providers to promote health, to prevent disease, and to assess, monitor, initiate, and modify medication use to assure that drug therapy regimens are safe and effective. The goal of Pharmaceutical Care is to optimize the patient's health-related quality of life, and achieve positive clinical outcomes, within realistic economic expenditures. To achieve this goal, the following must be accomplished:

A. A professional relationship must be established and maintained.

Interaction between the pharmacist and the patient must occur to assure that a relationship based upon caring, trust, open communication, cooperation, and mutual decision making is established and maintained. In this relationship, the pharmacist holds the patient's welfare paramount, maintains an appropriate attitude of caring for the patient's welfare, and uses all his/her professional knowledge and skills on the patient's behalf. In exchange, the patient agrees to supply personal information and preferences, and participate in the therapeutic plan. The pharmacist develops mechanisms to assure the patient has access to pharmaceutical care at all times.

B. Patient-specific medical information must be collected, organized, recorded, and maintained.

Pharmacists must collect and/or generate subjective and objective information regarding the patient's general health and activity status, past medical history, medication history, social history, diet and exercise history, history of present illness, and economic situation (financial and insured status). Sources of information may include, but are not limited to, the patient, medical charts and reports, pharmacist-conducted health/physical assessment, the patient's family or caregiver, insurer, and other healthcare providers including physicians, nurses, mid-level practitioners and other pharmacists. Since this information will form the basis for decisions regarding the development and subsequent modification of the drug therapy plan, it must be timely, accurate, and complete, and it must be organized and recorded to assure that it
is readily retrievable and updated as necessary and appropriate. Patient information must be maintained in a confidential manner.

C. **Patient-specific medical information must be evaluated and a drug therapy plan developed mutually with the patient.**

Based upon a thorough understanding of the patient and his/her condition or disease and its treatment, the pharmacist must, with the patient and with the patient's other healthcare providers as necessary, develop an outcomes-oriented drug therapy plan. The plan may have various components which address each of the patient's diseases or conditions. In designing the plan, the pharmacist must carefully consider the psycho-social aspects of the disease as well as the potential relationship between the cost and/or complexity of therapy and patient adherence. As one of the patient's advocates, the pharmacist assures the coordination of drug therapy with the patient's other healthcare providers and the patient. In addition, the patient must be apprised of (1) various pros and cons (i.e., cost, side effects, different monitoring aspects, etc.) of the options relative to drug therapy and (2) instances where one option may be more beneficial based on the pharmacist's professional judgment. The essential elements of the plan, including the patient's responsibilities, must be carefully and completely explained to the patient. Information should be provided to the patient at a level the patient will understand. The drug therapy plan must be documented in the patient's pharmacy record and communicated to the patient's other healthcare providers as necessary.

D. **The pharmacist assures that the patient has all supplies, information and knowledge necessary to carry out the drug therapy plan.**

The pharmacist providing Pharmaceutical Care must assume ultimate responsibility for assuring that his/her patient has been able to obtain, and is appropriately using, any drugs and related products or equipment called for in the drug therapy plan. The pharmacist must also assure that the patient has a thorough understanding of the disease and the therapy/medications prescribed in the plan.
E. The pharmacist reviews, monitors, and modifies the therapeutic plan as necessary and appropriate, in concert with the patient and healthcare team.

The pharmacist is responsible for monitoring the patient's progress in achieving the specific outcomes according to strategy developed in the drug therapy plan. The pharmacist coordinates changes in the plan with the patient and the patient's other healthcare providers as necessary and appropriate in order to maintain or enhance the safety and/or effectiveness of drug therapy and to help minimize overall healthcare costs. Patient progress is accurately documented in the pharmacy record and communicated to the patient and to the patient's other healthcare providers as appropriate. The pharmacist shares information with other healthcare providers as the setting for care changes thus helping assure continuity of care as the patient moves between the community setting, the institutional setting, and the long-term care setting.

Practice Principles

1. Data Collection

1.1 The pharmacist conducts an initial interview with the patient for the purposes of establishing a professional working relationship and initiating the patient's pharmacy record. In some situations (e.g. pediatrics, geriatrics, critical care, language barriers) the opportunity to develop a professional relationship with and collect information directly from the patient may not exist. Under these circumstances, the pharmacist should work directly with the patient's parent, guardian, and/or principal caregiver.

1.2 The interview is organized, professional, and meets the patient's need for confidentiality and privacy. Adequate time is devoted to assure that questions and answers can be fully developed without either party feeling uncomfortable or hurried. The interview is used to systematically collect patient-specific subjective information and to initiate a pharmacy record which includes information and data regarding the patient's general health and activity status, past medical history, medication history, social history (including economic situation), family history, and history of present
illness. The record should also include information regarding the patient's thoughts or feelings and perceptions of his/her condition or disease.

1.3 The pharmacist uses health/physical assessment techniques (blood-pressure monitoring, etc.) appropriately and as necessary to acquire necessary patient-specific objective information.

1.4 The pharmacist uses appropriate secondary sources to supplement the information obtained through the initial patient interview and health/physical assessment. Sources may include, but are not limited to, the patient's medical record or medical reports, the patient's family, and the patient's other healthcare providers.

1.5 The pharmacist creates a pharmacy record for the patient and accurately records the information collected. The pharmacist assures that the patient's record is appropriately organized, kept current, and accurately reflects all pharmacist-patient encounters. The confidentiality of the information in the record is carefully guarded and appropriate systems are in place to assure security. Patient-identifiable information contained in the record is provided to others only upon the authorization of the patient or as required by law.

2. Information Evaluation

2.1 The pharmacist evaluates the subjective and objective information collected from the patient and other sources then forms conclusions regarding: (1) opportunities to improve and/or assure the safety, effectiveness, and/or economy of current or planned drug therapy; (2) opportunities to minimize current or potential future drug or health-related problems; and (3) the timing of any necessary future pharmacist consultation.

2.2 The pharmacist records the conclusions of the evaluation in the medical and/or pharmacy record.

2.3 The pharmacist discusses the conclusions with the patient, as necessary and appropriate, and assures an appropriate understanding of the nature of the condition or illness and what might be expected with respect to its management.

3. Formulating a Plan
3.1 The pharmacist, in concert with other healthcare providers, identifies, evaluates and then chooses the most appropriate action(s) to: (1) improve and/or assure the safety, effectiveness, and/or cost-effectiveness of current or planned drug therapy; and/or, (2) minimize current or potential future health-related problems.

3.2 The pharmacist formulates plans to effect the desired outcome. The plans may include, but are not limited to, work with the patient as well as with other health providers to develop a patient-specific drug therapy protocol or to modify prescribed drug therapy, develop and/or implement drug therapy monitoring mechanisms, recommend nutritional or dietary modifications, add non-prescription medications or non-drug treatments, refer the patient to an appropriate source of care, or institute an existing drug therapy protocol.

3.3 For each problem identified, the pharmacist actively considers the patient's needs and determines the desirable and mutually agreed upon outcome and incorporates these into the plan. The plan may include specific disease state and drug therapy endpoints and monitoring endpoints.

3.4 The pharmacist reviews the plan and desirable outcomes with the patient and with the patient's other healthcare provider(s) as appropriate.

3.5 The pharmacist documents the plan and desirable outcomes in the patient's medical and/or pharmacy record.

4. Implementing the Plan

4.1 The pharmacist and the patient take the steps necessary to implement the plan. These steps may include, but are not limited to, contacting other health providers to clarify or modify prescriptions, initiating drug therapy, educating the patient and/or caregiver(s), coordinating the acquisition of medications and/or related supplies, which might include helping the patient overcome financial barriers or lifestyle barriers that might otherwise interfere with the therapy plan, or coordinating appointments with other healthcare providers to whom the patient is being referred.

4.2 The pharmacist works with the patient to maximize patient understanding and involvement in the therapy plan, assures that arrangements for drug therapy
monitoring (e.g. laboratory evaluation, blood pressure monitoring, home blood glucose testing, etc.) are made and understood by the patient, and that the patient receives and knows how to properly use all necessary medications and related equipment. Explanations are tailored to the patient's level of comprehension and teaching and adherence aids are employed as indicated.

4.3 The pharmacist assures that appropriate mechanisms are in place to ensure that the proper medications, equipment, and supplies are received by the patient in a timely fashion.

4.4 The pharmacist documents in the medical and/or pharmacy record the steps taken to implement the plan including the appropriate baseline monitoring parameters, and any barriers which will need to be overcome.

4.5 The pharmacist communicates the elements of the plan to the patient and/or the patient's other healthcare provider(s). The pharmacist shares information with other healthcare providers as the setting for care changes, in order to help maintain continuity of care as the patient moves between the ambulatory, inpatient or long-term care environment.

5. Monitoring and Modifying the Plan/Assuring Positive Outcomes

5.1 The pharmacist regularly reviews subjective and objective monitoring parameters in order to determine if satisfactory progress is being made toward achieving desired outcomes as outlined in the drug therapy plan.

5.2 The pharmacist and patient determine if the original plan should continue to be followed or if modifications are needed. If changes are necessary, the pharmacist works with the patient/caregiver and his/her other healthcare providers to modify and implement the revised plan as described in "Formulating the Plan" and "Implementing the Plans" above.

5.3 The pharmacist reviews ongoing progress in achieving desired outcomes with the patient and provides a report to the patient's other healthcare providers as appropriate. As progress towards outcomes is achieved, the pharmacist should provide positive reinforcement.
5.4 A mechanism is established for follow-up with patients. The pharmacist uses appropriate professional judgement in determining the need to notify the patient's other healthcare providers of the patient's level of adherence with the plan.

5.5 The pharmacist updates the patient's medical and/or pharmacy record with information concerning patient progress, noting the subjective and objective information which has been considered, his/her assessment of the patient's current progress, the patient's assessment of his/her current progress, and any modifications that are being made to the plan. Communications with other healthcare providers should also be noted.

Pharmaceutical care is a process of drug therapy management that requires a change in the orientation of traditional professional attitudes and re-engineering of the traditional pharmacy environment. Certain elements of structure must be in place to provide quality pharmaceutical care. Some of these elements are: (1) knowledge, skill, and function of personnel, (2) systems for data collection, documentation, and transfer of information, (3) efficient work flow processes, (4) references, resources and equipment, (5) communication skills, and (6) commitment to quality improvement and assessment procedures.

Knowledge, skill, and function of personnel

The implementation of pharmaceutical care is supported by knowledge and skills in the area of patient assessment, clinical information, communication, adult teaching and learning principles and psychosocial aspects of care. To use these skills, responsibilities must be reassessed, and assigned to appropriate personnel, including pharmacists, technicians, automation, and technology. A mechanism of certifying and credentialling will support the implementation of pharmaceutical care.

Systems for data collection and documentation

The implementation of pharmaceutical care is supported by data collection and documentation systems that accommodate patient care communications (e.g. patient contact notes, medical/medication history), interprofessional communications (e.g. physician communication, pharmacist to pharmacist communication), quality
assurance (e.g. patient outcomes assessment, patient care protocols), and research (e.g. data for pharmacoepidemiology, etc.). Documentation systems are vital for reimbursement considerations.

Efficient work flow processes

The implementation of pharmaceutical care is supported by incorporating patient care into the activities of the pharmacist and other personnel.

References, resources, and equipment

The implementation of pharmaceutical care is supported by tools which facilitate patient care, including equipment to assess medication therapy adherence and effectiveness, clinical resource materials, and patient education materials. Tools may include computer software support, drug utilization evaluation (DUE) programs, disease management protocols, etc.

Communication Skills

The implementation of pharmaceutical care is supported by patient-centered communication. Within this communication, the patient plays a key role in the overall management of the therapy plan.

Quality Assessment/Improvement Programs

The implementation and practice of pharmaceutical care is supported and improved by measuring, assessing, and improving pharmaceutical care activities utilizing the conceptual framework of continuous quality improvement.

This document will not cover each and every situation; that was not the intent of the Advisory Committee. This is a dynamic document and is intended to be revised as the profession adapts to its new role. It is hoped that pharmacists will use these principles, adapting them to their own situation and environments, to establish and implement pharmaceutical care.

(1)Although "drug therapy" typically refers to intended, beneficial effects of pharmacologic drugs, in this document, "drug therapy" refers to the intended, beneficial use of drugs - whether diagnostic or therapeutic - and thus includes
diagnostic radiopharmaceuticals, X-ray contrast media, etc. in addition to pharmacologic drugs. Similarly, "drug therapy plan" includes the outcomes oriented plan for diagnostic drug use in addition to pharmacologic drug use.

**ORGANIZATION OF MEDICINE PROVIDING IN PHARMACY**

Pharmacy establishment needs commodity supplies for providing of its continuous and rhythmic work.

The supplies of all medications belong to the commodity supplies, are on its balance and intended for the retail business. The commodity supplies of pharmacies includes commodities, which are present in a presence in pharmacy establishment and its structural subdivisions; commodities which are bought in and prepaid by this pharmacy establishment and left on responsible storage at suppliers; commodities which are handed over on processing (for example, medical vegetable raw material).

In pharmacy *commodity supplies can be concentrated*:

- in the separate department of supplies (hospital and interhospital pharmacies, central district pharmacies, pharmacies are legal entities, that have the structural subdivisions and others like that);
- in the prescription department of pharmacies with a right (license) for preparing of medications;
- in a general department, if functioning of other departments in pharmacy establishment is not foreseen.

**General Operational principles for good pharmaceutical procurement**

These objectives and principles have been developed and endorsed by the Interagency Pharmaceutical Coordination Group (IPC), involving the pharmaceutical advisers of the United Nations Children’s Fund (UNICEF), the United Nations Population Fund (UNFPA), the World Health Organization (WHO) and the World Bank.

The *aim* of this document is to improve pharmaceutical procurement practices in countries served by the IPC members. These operational principles for good
pharmaceutical procurement are not meant to regulate activities of international agencies, sovereign governments or private companies. They are presented strictly as a set of principles which can be reviewed and adapted by individual governments and public or private organizations in the process of developing their own internal procurement procedures.

The document is composed of four chapters.

Chapter 1 consists of a brief problem statement which illustrates the need for improvements in procurement practices.

Chapter 2 presents the four strategic objectives of pharmaceutical procurement which apply to any health system, whether it is public or private.

Chapter 3 presents twelve operational principles for good pharmaceutical procurement, grouped into four categories (management; selection and quantification; financing and competition; supplier selection and quality assurance).

Chapter 4 gives more information on the practical implementation of the twelve principles and some useful information on mechanisms to further improve the performance of the procurement system. A section of references and further reading is also included.

1. Problem statement

Pharmaceutical procurement is a complex process which involves many steps, agencies, ministries and manufacturers. Existing government policies, rules and regulations for procurement as well as institutional structures are frequently inadequate and sometimes hinder overall efficiency in responding to the modern pharmaceutical market.

Market constraints differ from country to country. Public sector drug procurement must take place in the context of both the local pharmaceutical market and the international market. In many countries public health officials have limited experience in designing an optimal procurement system to fit their market context. An increasing number of countries have moved, or are moving, away from a pharmaceutical procurement and distribution system which is totally operated by the
public sector, and are investigating various options for involving the private sector in order to enhance public health.

Summary of main problems

- inadequate rules, regulations and structures;
- public sector staff with little experience in responding to market situations;
- absence of a comprehensive procurement policy;
- government funding which is insufficient and/or released irregularly;
- donor agencies with conflicting procurement regulations;
- fragmented drug procurement at provincial or district level;
- lack of unbiased market information;
- lack of trained procurement staff.

Strategic objectives for good pharmaceutical procurement

The operational principles for good pharmaceutical procurement, which form the bulk of this document, are based on four strategic objectives. Both the strategic objectives and the operational principles are relevant to any public sector drug supply system, no matter what combination of public and private services is used to manage the system.

Four strategic objectives of pharmaceutical procurement

1. Procure the most cost-effective drugs in the right quantities
2. Select reliable suppliers of high-quality products
3. Ensure timely delivery
4. Achieve the lowest possible total cost

1. Procure the most cost-effective drugs in the right quantities

The first strategic objective is that all organizations responsible for procurement, whether they are public, private non-profit or private for-profit, should develop an essential drugs list to make sure that only the most cost-effective drugs are purchased. Procedures must also be in place that accurately estimate procurement
quantities in order to ensure continuous access to the products selected without accumulating excess stock.

2. Select reliable suppliers of high-quality products

The second objective is that reliable suppliers of high-quality products must be (pre-)selected, and that active quality assurance programs involving both surveillance and testing must be implemented.

3. Ensure timely delivery

The third strategic objective is that the procurement and distribution systems must ensure timely delivery of appropriate quantities to central or provincial stores and adequate distribution to health facilities where the products are needed.

4. Achieve the lowest possible total cost

The fourth objective is that the procurement and distribution systems must achieve the lowest possible total cost, considering four main components:

- the actual purchase price of drugs;
- hidden costs due to poor product quality, poor supplier performance or
  - short shelf-life;
  - inventory holding costs at various levels of the supply system;
  - operating costs and capital loss by management and administration of the procurement and distribution system.

Operational principles for good pharmaceutical procurement Efficient and Transparent Management

1. Different procurement functions and responsibilities (selection, quantification, product specification, pre-selection of suppliers and adjudication of tenders) should be divided among different offices, committees and individuals, each with the appropriate expertise and resources for the specific function.

2. Procurement procedures should be transparent, following formal written procedures throughout the process and using explicit criteria to award contracts.
3. Procurement should be planned properly and procurement performance should be monitored regularly; monitoring should include an annual external audit.

4. Public sector procurement should be limited to an essential drugs list or national/local formulary list.

No public or private health care system in the world can afford to purchase all drugs circulating in the market within its given budget. Resources are limited and choices have to be made. A limited list of drugs for procurement, based on an essential drugs list or drug formulary, defines which drugs will be regularly purchased and is one of the most effective ways to control drug expenditure. A nationally developed formulary or selection based on the essential drugs concept has been used in both industrialized and developing countries' health systems for more than twenty years. This allows the health system to concentrate resources on the most cost-effective and affordable drugs to treat prevailing health problems. The selection of drugs based on a national formulary or national list allows for concentrating on a limited number of products. Larger quantities may encourage competition and lead to more competitive drug prices. Reducing the number of items also simplifies other supply management activities and reduces inventory-carrying costs.

Practical aspects. Some public and private health systems strictly limit procurement to drugs listed on an essential drugs list. However, in most cases some mechanism exists to address special needs, allowing the occasional procurement of non-list drugs after approval by senior officials.

5. Procurement and tender documents should list drugs by their International Nonproprietary Name (INN), or generic name.

The INN is widely accepted as the standard for describing drugs on a procurement list or tender request. Although this is most obviously applicable when purchasing drugs which are available from multiple sources, generic description should also be used when purchasing single source products. When purchasing products which present potential problems with pharmaceutical equivalence or bio-
equivalence the procurement request should specify the quality standards but not mention specific brands.

Practical aspects. This does not mean that brand-name suppliers should be barred from tender participation; they may offer the most cost-effective product, and in fact may offer more competitive prices for certain branded drugs than generic competitors. However, all drugs supplied to the public health system should be properly labelled in accordance with standards laid down by law (or in accordance with labelling instructions), including the INN featured prominently in addition to the brand name that may be on the label.

6. Order quantities should be based on a reliable estimate of actual need.

An accurate quantification of procurement requirements is needed to avoid stock-outs of some drugs and overstocks of others. In addition, if suppliers believe the estimated procurement quantities are accurate, they are more willing to offer the lowest competitive price on an estimated-quantity supply contract.

Practical aspects. Past consumption is the most reliable way to predict and quantify future demand, providing that the supply pipeline has been consistently full and that consumption records are reasonably accurate. Such consumption data must be adjusted in the light of known or expected changes in morbidity patterns, seasonal factors, service levels, prescribing patterns and patient attendance. The downside of basing quantification only on past consumption is that any existing patterns of irrational drug use will be perpetuated. In many countries consumption data are incomplete or do not reflect real demand because the supply pipeline has not always been full and drug use has not always been rational. In such cases the morbidity-based and extrapolated consumption techniques may be used to estimate procurement requirements. These techniques, particularly the morbidity-based method, should also be used periodically to check on the rationality of past consumption, by comparing actual consumption with the estimated need to treat common diseases based on standard treatment protocols and epidemiological data. When funds are not available to purchase all drugs in the quantities which were estimated to be needed, it is
necessary to prioritize the procurement list to match available financial resources. Various techniques such as VEN (vital, essential and nonessential) Analysis, Therapeutic Category Analysis and ABC Analysis can be used to select priorities and reduce the quantities of less cost-effective drugs. A VEN priority list should be defined in advance of any decision related to reducing procurement.

7. Mechanisms should be put in place to ensure reliable financing for procurement.

Good financial management procedures should be followed to maximize the use of financial resources.

Potential sources of funds for pharmaceutical procurement include government financing, user fees, health insurance, community co-financing and donor financing. These options vary in terms of their efficiency, equity and sustainability. The most important considerations for procurement are total funds available, adequate access to foreign exchange and the regularity with which funds are available. It is the responsibility of governments and senior managers to establish appropriate and reliable funding for public drug procurement as a high priority, and to implement mechanisms which provide adequate funding on time to support public sector procurement.

Efficient financial management systems are especially important if funds are limited and procurement priorities must be set. Being able to order drugs when needed and to pay for them on delivery has a very positive effect on reducing both prices and stock-outs and on increasing supplier confidence in the procurement system. Prompt, reliable payment can have as great an influence on bringing down drug prices as bulk discounts.

Practical aspects. Financial mechanisms such as decentralized drug purchasing accounts may help the procurement cycle to operate independently of the treasury cycle. Revolving drug funds can help achieve this separation by establishing their own bank.
accounts and their own working capital. An aspect of financing which is sometimes overlooked is funding for the procurement process itself. Procurement services may be part of the warehouse and distribution operation or set up as a separate office. In either case, salaries and operational costs of the procurement office must be covered by the users.

8. Procurement should be effected in the largest possible quantities in order to achieve economies of scale; this applies to both centralized and decentralized systems.

Larger procurement volume makes favourable prices and contract terms more likely, by increasing suppliers’ interest in bidding and by providing them with an incentive to offer a competitive price.

Practical aspects. A higher volume for single items may be achieved through pooling of procurement volume from many facilities or from several States or countries, by restriction of the drug list or by elimination of duplication within therapeutic categories.

9. Procurement in the public health sector should be based on competitive procurement methods, except for very small or emergency orders.

Justification and explanation

There are four main methods for purchasing drugs. Three of them are competitive: restricted tenders, open tenders and competitive negotiations. The fourth method is direct negotiation with a single supplier. Since inducing supplier competition is a primary key to obtaining favourable pricing, the public sector should use competitive methods for all but very small or emergency purchases. This assumes, of course, that there are multiple suppliers for the items needed.

10. Members of the purchasing groups should purchase all contracted items from the supplier(s) which hold(s) the contract.

11. Prospective suppliers should be pre-qualified, and selected suppliers should be monitored through a process which considers product quality, service reliability, delivery time and financial viability.
Pre- and post-qualification procedures help to eliminate substandard suppliers, if properly managed. Pre-qualification is the procedure of evaluating supplier capacity and reputation before bids are solicited for specific products. This is the preferred procedure, especially for ongoing drug procurement systems. Although substantial time is required to establish an initial list of pre-qualified suppliers, once this has been done the lowest pre-qualified tenderer for each product is deemed to be qualified, which expedites adjudication and contract award.

Post-qualification evaluates the suppliers after bids have been received. If there are numerous offers from unknown suppliers there may be long delays in awarding contracts, as it will be necessary to validate suppliers’ capacity to supply good-quality products.

12. Procurement procedures/systems should include all assurances that the drugs purchased are of high quality, according to international standards.

The twelve operational principles for good pharmaceutical procurement practices aim to improve pharmaceutical procurement by ministries of health, supply agencies, nongovernmental organizations and other organizations involved in drug supply. When introducing and using these principles, the following should be kept in mind.

The operational principles should be used to develop standard operational procedures

These twelve principles constitute the minimum conditions for a reliable and cost-effective drug procurement system. They should be used as the basis for developing a set of more detailed standard operational procedures, taking into account the specific institutional circumstances and market conditions under which the system must operate.

Standard operational procedures must be actively implemented and monitored

The operational principles and the standard operational procedures must be supported by the national drug policy, regulations and legislation. International agencies and other external organizations which give technical or financial support to
the national drug supply system should be asked to support and promote their implementation.

*Good drug procurement is only possible within a well-managed drug supply system*

Standard operational procedures can improve drug procurement only if they are implemented within a well-managed drug supply agency. This agency may be a classic government central medical store, an autonomous or semi-autonomous supply agency, an independent nongovernmental agency or some other form of supply agency. Critical factors for the performance of drug supply agencies include: qualified senior management; adequate personnel policies; a broad-based board for planning and following up the overall work; proper contract terms between the government and the contractor; and reliable financing and accounting systems.

*The right purchasing and inventory control model should be chosen*

Procurement can be done through a single annual tender, through a schedule of periodic tenders throughout the year, through a perpetual inventory system in which procurement is initiated as soon as stocks fall below a certain level, or through a combination of such systems. The choice depends on a variety of factors, including the type of drugs used (expensive drugs, short shelf-life, high or low consumption rate), the geographical situation, local production capacity, total consumption and others. The geography is important since more isolated areas tend to purchase less frequently. Local production capacity allows greater flexibility and more frequent deliveries. High-volume items may be purchased more frequently throughout the year. The choice of purchasing and inventory model affects the direct cost of the drug, staff requirements (frequent purchases need more staff time) and inventory costs (less frequent procurement requires more warehouse space). At a certain stage, an effective computerized system should be introduced to manage inventory control. This should probably be done in phases, with the system developed or backed up by a local company. A well-functioning manual inventory control system can be converted into a computerized one.
Legislation and regulations may need to be adapted

National legislation and regulations provide the necessary legal foundation for procurement procedures, contract enforcement, financial authority, staff accountability and other critical aspects of procurement. Existing legislation and regulations may be fully consistent with the twelve core principles. Often, however, legislative or regulatory changes will be needed.

A common problem is that the general rules for drug procurement by the public sector do not take account of the specialized procurement requirements of buying pharmaceuticals. The challenge may be not only to identify the changes which are needed, but also to convince the relevant legal and financial authorities that pharmaceutical procurement does in fact require a different approach. Some examples of specific requirements are: separation of the key procurement functions, the need for financial audit, mandatory use of generic names, the need for product registration which should also apply to the public sector but is often ignored) and formal supplier qualification. Other related issues are pricing policies and ethical criteria for drug promotion.

Capacity needs to be built

Pharmaceutical procurement is a specialized professional activity which requires a combination of knowledge, skills and experience. Too often drug supply agencies are staffed by individuals with little or no specific training in pharmaceutical procurement. It is essential, therefore, that staff in key procurement positions be well trained and highly motivated. Training may be organized through national or international courses, through apprenticeships with international supply agencies or supply agencies in other countries, or by enlisting experienced short-term or long-term support from external technical advisers.

International and bilateral agencies should support the national procurement system

Development assistance through loans, grants and other financial mechanisms is intended to contribute to long-term health sector development. External technical
assistance is intended to build local capacity and to develop sustainable systems, and should therefore be consistent with the policies of the country. It is essential that development assistance reinforces good pharmaceutical procurement practices and aims at sustainability, rather than undermining or delaying the national development of such practices. From a development point of view, investing in teaching good procurement practices may be more important than just procuring the drugs. Thus international, multilateral and bilateral agencies may need to review their own procedures, requirements and technical advice in the light of the present document. In the same vein, WHO’s.

**Contents of contracts on the purchase-sale of commodities, their basic parts**

Pharmacy is mainly trading enterprise, therefore the rational organization of the supply system is very important. The providing with medicines organised according to the contracts.

Contract is a major legal document. It consists of the following parts:
- preamble - a salesman and buyer and their legal status are determined;
- subject of agreement – pointing of sum of contract, type of the commodity, subject of the purchase-sale;
- obligations of parties;
- forming of prices and computations;
- base terms of delivery;
- arbitration – method of decision of the vexed questions;
- force-majeure determines the independent of parties circumstances, entailing breaking of contracts: military operations, revolutions, natural calamities and etc.

At the end of contract the legal addresses of partners are indicated (places, on which enterprises are incorporated in the organs of power).

The sample of the contract is shown below.
CONTRACT # 00-97 UKR/ XXXX 1

Company ‘XXXX”, Kiev, Ukraine in the person of Mr. I. Ivanov, General director acting in accordance with the Statute and Mr. P. Petrov, commercial director acting in accordance with the General Warrant, hereinafter referred to as the Buyer on the one hand and

PFIZER H. C. P. CORPORATION, a USA based company in the person of Mr. Kurt. H. Hahn, Regional Manager of PFIZER CEER, Zaventem, Belgium, acting in accordance with the Statute hereinafter referred to as the Seller on the other hand have agreed as follows:

1. SUBJECT OF THE CONTRACT.
1.1 The Seller has sold and the Buyer has bought on CIP KIEV airport EORISPOL terms (INCOTERMS-90), the goods listed in the specification which is an integral part of the present Contract.
1.2 The Seller will deliver to the Buyer on the CIP KIEV airport BORISPOL terms (INCOTERMS-90), the goods listed in the specification to the present Contract.

2. PRICE AND TOTAL VALUE OF THE CONTRACT.
2.1 Prices of the delivered goods are set in USD.
2.2 The prices include the cost of packing, marking, insurance and delivery on the mentioned terms.
2.3 The total value of the Contract is USD 00 000,00.
2.4 Prices shall be firm and stable during the term of the Contract, they are valid only for this Contract and cannot be negotiated or referred with other trade organizations.

3. DATES OF DELIVERY.
3.1 The delivery of the products specified in the present Contract will be effected within 30 days after the signature of the Contract and a written confirmation of the
Buyer to accept the goods.

3.2 The delivery date shall be the date of the Bill of Lading (truck waybill or airwaybill).

4. TERMS OF PAYMENT.

4.1 Payments and documents against payment for the goods, delivered under the present Contract, is effected in form of 100 % payment at 00 days from the Invoice date to the Seller’s account:

PFIZER H. C. P. CORPORATION
432-4408232-16
235 East 42nd Street
New York NYJO017
do Central & Eastern Europe Region HogeWei 10
B-1930 Zaventem, Belgium held with KREDIETBANK Brabant West Corporate
Rue de la Technologie 1,
1082 BRUXELLES
Belgium
SWIFT: KREDBEBB
Fax n: 02/469-01-22
The currency of payment is USD.

4.2 The Seller shall provide the following documents:

1. Seller’s invoice (1 original and 4 copies).
2. Bill of Lading 9 (1 original and 2 copies).
3. Packing lists (5 copies).
5. Certificate of origin.
5. GUARANTEE.
5.1 The Seller shall be responsible for the change of properties, spoiling of goods after their delivery to the Buyer as well if such change of properties, damage or spoiling came about as a result of the Seller’s breach of terms of delivery specified herein.

6. PACKING AND MARKING.
6.1 Every precaution shall be taken by the Seller to ensure that the goods are packed in a secure manner appropriate to the nature of the goods and the conditions of storage, transport and transshipment likely to be used for the goods.
6.2 Each shipment shall be accompanied by packing list. Marking shall be clearly done in indelible ink. Marking shall bear the following information:
- Buyer’s name
- Contract No
- Gross weight
- Net weight
- Keep in dry place
- Handle with care
- Up
- Case No
6.3 The Seller shall be responsible for all losses and for damages resulting from the incorrect marking.

7. NOTIFICATION OF SHIPMENT.
7.1 Within 24 hours of the goods’ shipment the Seller shall fax to the Buyer the following information:
- Date of shipment
- Contract No of Lading No
- Boxes quantity
- Gross weight
8. PENALTIES.
8.1 If the payment for the delivered goods is delayed for more than depicted in the point 4.1 of the present Contract and not having discussed the abovementioned with the Seller, the Buyer shall pay to the Seller a forfeit of 0,05% of the non-paid amount of the invoices for every day of delay.
8.2 If the shipment of medicines is delayed for more than 30 days, the Buyer shall have the right to cancel the contract without any compensation for damages which the Seller may suffer in connection with the cancellation of the Contract.

9. CLAIMS.
9.1 In case of the non-conformity of the quality, range and quantity of goods to the terms of the Contract the Buyer shall have the right to send the claims to the Seller within 1 (one) month from the date of the arrival of goods at the consignee’s warehouse.
The claim shall be deemed justified if confirmed by an Act of Expertise by a competent state organization.

10. FORCE MAJEURE
10.1 Neither party will be responsible for a complete or partial non fulfillment of any of its obligations if such nonfulfillment results from circumstances beyond its control, including natural phenomena, war and acts of war actions. If any of such circumstances directly affected the performance of obligation in the Contract, this time period is extended correspondingly for a period during which such circumstance lasts. Availability of FORCE MAJEURE circumstances should be confirmed by Trade Chamber of that party affected by

11. ARBITRATION.
11.1 Any disputes or disagreements that may arise out of for in connection with the execution hereof shall, if possible, be settled by the negotiations between the parties.
If the parties do not come to an agreement the matter shall be submitted for the arbitration to the CII in Paris.
The Arbitration’s award shall be final and binding upon both parties.
Material law of France will be applied.

12. OTHER TERMS CONDITIONS.

12.1 All appendices hereto shall be an integral part hereto.
12.2 To supply the lots with patient leaflets in Russian in accordance with the quantity of the delivered goods.
12.3 The Expire date of the drugs is to be clearly written in the packs and have no less than 70%.
12.4 The present Contract shall become effective on the date of its signature and shall expire in 31.03.98. if the parties have duly fulfilled their obligations under the present Contract.
12.5 The present Contract shall be signed in two copies in Russian and English, one copy for each party.
12.6 All licenses and charges, including bank commissions, taxes and customs such circumstances.

AND

duties on the territory of the Buyer’s country, related to the execution hereof, shall be paid by the Buyer at his expense, on the territory of the Seller ‘s country by the Seller.
12.7 Under the present Contract and according to the Seller’s request the Buyer is to provide the information of the stock of Pfizer’s goods in warehouses.
12.8 The parties have agreed the Buyer will be promoting the Pfizer drugs in Ukraine. Payment for the actions is effected by drugs by the Seller on the basis of the invoice issued by the Buyer.

13. LEGAL ADDRESSES.
THE ORGANIZATION OF STORAGE DEPARTMENT

The storage department (or person, which is responsible for addition to the commodity supplies and their storage) carries out:

- determination of current deficit of medicine in pharmacy;
- timely order of medicines;
- organization of acceptance of commodity in pharmacy and its storage;
- providing of other departments with medicines;
- organization of purveyances preparing, concentrates and conducting of packing works.
Acceptance of commodity from a supplier (factory-producer, wholesale firm and others like that) in pharmacy establishment is carried out by a commission, or responsible person, that is appointed by the order.

At presence of divergences, a supplier is to be put in fame about such divergences in the day of receipt or not later than a next day after the receipt these facilities (by a telephone, by fax, teletype or telegram).

For the registration or commodity acceptance in pharmacy establishment the notebook for “entrance control”, in which is fixed: record, date of receipt of commodity, his name, series, amount, name of supplier, who accepted and who checked up a commodity.

At the receipt of medications of “angro” their additional analysis on accordance by the high-quality reactions is conducted, about what is necessarily fixed in the special magazine.

Storage of the medications and other commodities of pharmacy assortment are carried out pursuant to the rules. For this purpose pharmacy establishment must have the necessary apartments that must answer all requirements of operating normatively-technical document. Pursuant to the set norms they must be provided with protective and fire-prevention facilities.

In the apartments for storage a certain temperature and humidity of air must be supported, for the supervisions after which the apartments must be equipped by thermometers and hygrometers.

In the apartments of storage medications take place separately:

☑️ in accordance with toxicological groups: poisonous and narcotic matters; drastic matters and general medicines.

In addition to this medicines also must be kept pursuant to the operating orders:

☑️ in accordance with pharmacological groups;
☑️ depending on the method of the use (internal, external);
☑️ medications of “angro” accordingly with the aggregate state (liquid separately
from friable, gaseous and others like that);
☑ in accordance with physical and chemical properties of medications and influencing of different factors of external environment;
☑ taking into account the set terms of fitness, and also character of different medical forms.

Persons which are responsible for storage of medications also carry out the control after the terms of their expiry date. For this purpose they conduct the special magazine or card index.

It follows to keep the wares of the medical setting separately after groups: rubber wares, wares from plastics, bandaging facilities and auxiliary materials, wares of medical technique.

Inhibition of requirements of this instruction is obligatory for all pharmacy establishments, regardless of their submission and patterns of ownership.

**Apartments and equipment of storage department.**

Department must have adequate facilities for the reception of goods, their storage and distribution:

- The required area or room for the reception of the goods;
- Areas or storage facilities for the goods (drugs, packaging materials, auxiliary materials, herbal plants);
- Room for service of hospitals (for receiving and processing orders, forwarding);
- Room for laboratory and packing work.

*Equipment of workplaces:* dispenser for filling liquid, a device for dispensing and packaging of powders, a device for crimping caps on bottles, apparatus for filtering fluids, grinding and mixing of powders, magnetic stirrer.

*Duties of the pharmaceutical personnel.*

Head of the department his deputies, pharmacists and packers are working in the department.

*Duties of the department head and his deputies:*
1. Drawing up of orders requirements.
2. Control over the availability of the pharmacy the full range of medicines and the organization of their store.
3. Reception of goods from the supplier.
4. Accounting and reporting of goods moving in the department.
5. Providing goods to other departments and pharmacy’s structural units.
6. Realization of goods to health facilities and other organizations.

**Duties of the pharmacist:**

1. Laboratory work (production of concentrates, intermediate products) for an assistant room.
2. The distribution of work between the packers and the receiving from them finished products.
3. Control over the correct design of laboratory glassware with stocks of drugs.
4. Preparation of orders for other departments of pharmacy, health facilities and structural subdivision.
5. Taking part in the reception of the goods.
6. Control over the correct placement of products during storage.
7. Monitoring of compliance with the order of the pharmaceutical and health regime in the department.
8. Paperwork for accounting of laboratory and packing work.

**Storage of drugs**

Who administer or dispense drugs shall comply with the following standards:

(1) Each drug storage area shall be maintained in a clean and orderly condition.
   (i) The storage area shall be dry, well ventilated and well lighted. Provision shall be made for adequate dust, humidity and temperature controls to ensure drug stability.
   (ii) The storage area shall contain only drugs and related supplies and equipment which are necessary for the administration and dispensing of drugs to the dentist’s own patients.
(iii) Drugs in the storage area shall be accurately labeled. Until a drug is administered or dispensed to a dental patient, it shall be kept in the manufacturer’s original container showing the manufacturer’s lot number and the expiration date.

(iv) Drugs in the storage area shall be free from adulteration. Appropriate procedures shall be established to minimize the hazards of cross contamination.

(v) Outdated or deteriorated drugs shall be identified as such and shall be segregated in the storage area pending their return to the manufacturer or their appropriate disposal. The dentist shall maintain records reflecting the final disposition of these products.

(2) Controlled substances shall be stored in a substantially constructed, locked container such as a cabinet or safe. Access to the locked container where controlled substances are kept in order to clean, replenish supplies or perform other necessary functions shall be allowed only when a dentist is present and supervising.

Store vaccines in an area away from refrigerated/frozen medications to avoid confusion. Do not store vaccines in the refrigerator door shelf where temperature fluctuations may be greater.

Protect vaccines from light, especially MMR

**Temperature**

All drugs shall, at all times, be stored at a temperature which complies with the standards established by the current volume of the Pharmacopeia.

**Prescription Drugs**

All prescription drugs shall be stored in an area which is under the immediate control

**Area, Space and Fixtures**

(a) Pharmaceuticals, library and equipment shall be housed in a well lighted and ventilated room or department with clean and sanitary surroundings devoted primarily to the compounding of prescriptions. This portion of a pharmacy shall have an area of not less than 200 square feet. No area shall be included in the calculation of the minimum area required by this section unless that area is used exclusively for the storage, manufacture, compounding, and dispensing of drugs.
(b) The space primarily devoted to the compounding of prescriptions shall be equipped with:

1. Necessary counters and storage cabinets;
2. A sink with hot and cold running water; and
3. Refrigeration storage equipment used capacity exclusively for drugs.

(c) Upon written request by an institution the board shall waive minimum area requirements for institutional pharmacies upon a showing that the extent of pharmaceutical services provided does not require the full 200 square feet.

(a) That portion of a pharmacy wherein drugs are stored, manufactured, compounded or dispensed, shall, when the pharmacy is open, be so designed and constructed as to prevent entry into that area by any person or persons without the knowledge of the pharmacist then on duty, or when the pharmacy is not open to the public, by the activation of an alarm.

(b) The pharmacy shall be equipped with an alarm system which, when activated, shall emit a signal which is:

1. Audible to the average person situated outside the building in which the pharmacy is located, at least 100 feet from any point of that building, or the public highway closest to that building, whichever is greater; or
2. Observable by a law enforcement or security officer situated in a station of the law enforcement organization having jurisdiction over the area in which the pharmacy is located or in an office of a security organization serving the area in which the pharmacy is located.

(c) In order to be adequately designed and constructed, within the meaning of this section, a pharmacy shall be equipped with a door or doors capable of being locked.

Good storage practice

WHO's goal in medicines is to help save lives and improve health by ensuring the quality, efficacy, safety and rational use of medicines, including traditional
medicines, and by promoting equitable and sustainable access to essential medicines, particularly for the poor and disadvantaged

**Manual on Appropriate practice of storage of pharmaceutical production**

1. Introduction

The given manual is intended for all workers concerning storage, transportation and distribution of pharmaceutical production. It is closely connected to other manuals recommended by the Expert committee the CART under specifications of pharmaceutical preparations, such as:

- Appropriate practice of trade and distribution (GTDP) pharmaceutical initial materials;
- Test of stability of the pharmaceutical production containing well-known substances of medical products in usual medicinal forms (the information given in connection with registration of preparations);
- Appropriate industrial practice (GMP);
- Cold circuit, mainly for vaccines and biological preparations;
- The international Pharmacopoeia.

The given manual represents addition to set forth above documents and contains the description of the special measures necessary for correct storage and transportation of pharmaceutical production. These measures if necessary can be adapted for a concrete situation, under condition of observance of all quality standards.

The given manual is applicable not only to manufacturers of the medical goods, but also to importers and suppliers of pharmaceutical production, to distributors, drugstores and hospitals. The manual should be used in view of a kind of activity of the enterprise where storage of pharmaceutical production takes place. It is necessary to observe national and regional requirements also.

2. A glossary

The definitions of some terms used in the given manual resulted below, are formulated in view of terminology of modern acts and recommendations.
Active pharmaceutical component — Substance or a mix of substances which are intended for use in manufacture of a medical product, and also what at use in manufacture of this preparation become its working substance. Such substances should render pharmacological or other direct influence at diagnostics, treatment, simplification of symptoms or preventive maintenance of disease, and also to influence structure or functions of an organism.

Auxiliary substance — The substance which is distinct from an active component, past tests for safety and included in structure of a medical product, that:

- to facilitate processing a medical product during manufacture;
- to protect, support or raise(increase) stability, bioavailability or bearableness of a preparation;
- to help with identification of a product;
- to improve any other parameter of safety and efficiency of a preparation during storage or applications.

Expiration date of the validity — The date specified on individual packing (it is usual on a label) medical product up to which the preparation should correspond to specifications under condition of correct storage. For each set of the goods this date is defined(determined) by summation of a period of storage and date of manufacturing.

Date of repeated testing — Date when the material should be repeatedly tested with the purpose of an establishment of its suitability to further use.

Pollution — Undesirable entering impurity of a chemical or microbic origin or alien substances into an initial material either an intermediate or final product during manufacturing, sampling, packings or repackings, storages or transportations.

Manufacturing — All operations on creation of a pharmaceutical product, from reception of materials, their processing, packing and repacking, including marks and remarking, before reception of a final product.

Marks — Process of a choice of a correct label with all necessary information with the subsequent check and connection of a label.
Material — The general term used for a designation of an initial material (active pharmaceutical components and auxiliary substances), reagents, solvents, intermediate products, a packing material and labels.

Cross contamination — Pollution of an initial material, an intermediate product or a final product other initial material or a product during manufacture.

The supplier — The person providing delivery of pharmaceutical production on demand. Suppliers can be agents, intermediaries, distributors, manufacturers or sellers. As a rule, suppliers should be authorized by competent bodies.

Manufacture — Operations on purchase of materials and products, manufacturing, quality assurance, release, storage and distribution of an end-product, and also accompanying checks.

Packing material — A material, including printed, used for packing pharmaceutical production, excepting external packing for transportation and loadings. The packing material can be initial or secondary, depending on, whether it(he) enters into direct contact to a product.

Pharmaceutical product — A medical product intended for the person, or the veterinary product submitted in the final medicinal form or as an initial material for use in the given medicinal form, subject to check within the framework of the legislation both exporting, and the importing state.

Storage — The period of storage of pharmaceutical production till the moment of its use.

3. The personnel

3.1. On any site of storage (for example, at the manufacturer, the distributor, the wholesaler, in a drugstore or hospital) should be enough of qualified personnel to provide preservation of quality of pharmaceutical production. Qualification of the personnel should correspond to the state norms.

3.2. The personnel should pass training to appropriate practice of storage, the legislation, procedures and security measures.
3.3. Employees should pass special training and observe standards of personal hygiene and sanitary.

3.4. The employees working in a zone of storage, should carry protective or the working clothes corresponding to carried out work.

4. A room and the equipment

Room for storage of production

4.1. It is necessary to keep up, that in rooms for storage of pharmaceutical production did not suppose extraneous persons.

4.2. The room should be spacious enough to provide the ordered storage of various categories of materials and products, namely: initial and packing materials, intermediate products, finished goods, products on quarantine, and also defective, returned and withdrawn production.

4.3. The room for storage of production should be designed or converted so that to provide satisfactory conditions of storage. In particular, the room should be clean, dry, with comprehensible temperature. If special conditions of storage are necessary (for example, the temperature or relative humidity), it is necessary to provide these conditions, periodically to check, keep up parameters and to fix them. Materials and pharmaceutical products should not be stored on a floor, and around of them there should be enough place for cleaning and survey. Pallets should be in good condition and clean.

4.4. The room for storage of production should be clean, it is impossible to suppose congestions of dust or occurrence of wreckers and parasites. It is necessary to make and in writing to fix the program of actions under the sanitary control where periodicity and methods of cleaning of a room will be specified; the program дезинсекции and deratization. Means for desinsection and deratization should be safe, exclude risk of pollution of materials and pharmaceutical products. It is necessary to develop special procedures on cleaning the scattered medicines with the purpose of full elimination and prevention of pollution of other products.
4.5. Compartments of loading and unloading should protect materials and products from weather influences. The room where reception of the goods is made, should be equipped so that containers with the received materials and preparations in case of need could be cleaned before sending on storage.

4.6. The room in which preparations are kept on quarantine, should be precisely designated and access in it should be limited and allowed only to the authorized personnel. Any system replacing physical isolation, should provide adequate protection. For example, it is possible to use the computerized system provided that it is recognized reliable in restriction of access.

4.7. For sampling initial materials the separate room with corresponding controllable conditions should be removed. If sampling is made in a room for storage of production, it is necessary to take care of prevention of pollution or cross kontamination. It is necessary to develop corresponding procedures on cleaning a room for sampling.

4.8. For storage of defective, returned, withdrawn and delayed production the separate territory isolated physically or other reliable equivalent way (for example, electronic) should be allocated. Such products and materials, and also places of their storage should be precisely designated.

4.9. Highly active and radioactive materials, narcotics both other dangerous materials and pharmaceutical products, and also fire-and explosive substances (for example, inflammable liquids and firm substances, gases under pressure) should be kept in specially allocated places equipped with additional means of safety and protection.

4.10. With materials and pharmaceutical products it is necessary to address according to principles of the Appropriate industrial practice (GMP).

4.11. Materials and pharmaceutical products should be kept so that to not admit pollution, mixing and cross contamination.

4.12. Materials and pharmaceutical products should be kept in the conditions providing preservation of quality, and their stock should be updated constantly. First
of all it is necessary to get rid of production at which working life (a principle « first expired/first out » (FEFO)) expires.

4.13. The defective materials and pharmaceutical products should be identified and sent on storage in the quarantine conditions which are not admitting uses of production before acceptance of the final decision on their destiny.

4.14. Narcotic preparations should be kept according to the international conventions and national acts for a revolution of drugs.

4.15. The damaged products should be withdrawn and placed separately.

4.16. Illumination in rooms for storage of production should provide exact and safe performance of all operations.

**Conditions of storage**

4.17. Conditions of storage of pharmaceutical products and materials should correspond to requirements of a label, based on results of researches of stability (see the appendix).

**The control over conditions of storage**

4.18. It is necessary to fix fluctuations of temperature. The equipment used for supervision, it is necessary to check on a regular basis, and results of checks to write down and keep. All records of supervision should be kept, at least, one year after expiry of the term of the validity of a material or a product, or according to the national legislation. The card of temperatures should show an identical temperature mode in all a room. It is recommended to place gauges of temperature in places where its fluctuations are most probable.

4.19. It is necessary to carry out calibration of the equipment of supervision on a regular basis.

**5. Requirements on storage of production**

**The documentation: written instructions and reports**

5.1. It is necessary to keep written instructions, and also reports on all activity in rooms for storage of production, including work with products with the expired working life. These instructions and reports should describe clearly procedures of
storage and reflect movings materials, pharmaceutical products and information within the limits of the organization on a case of occurrence of necessity of a response of a product.

5.2. For each kept material or a product it is necessary to have the constant information, in a written or electronic kind, with the instruction of conditions of storage, any precautions and dates of repeated testing. Always it is necessary to observe requirements of the Pharmacopoeia and the current legislation.

5.3. It is necessary to keep reports on each reception of the goods. These reports should contain the description of the goods, the data on quality, quantity(amount) and the supplier, number of a (set) given by the supplier, date of reception, number of a set given at reception, and an expiration date of the validity. If the national legislation orders to keep this information during the certain period, it is necessary to observe this instruction. (Otherwise this information it is necessary to keep one more year after expiry of the term of the validity of the received materials or products).

5.4. It is necessary to conduct record of materials and pharmaceutical products at reception and sending; records are made to a specific attribute, for example under number of a set.

Marks and containers

5.5. Materials and pharmaceutical products should be kept in the containers which are not influencing quality of production and at it providing reliable protection against external influences, in particular and from bacterial infection.

5.6. Containers should be accurately marked: it is necessary to specify, at least, the name of a material, number of a set, working life or date of repeated testing, a condition of storage and the reference to the pharmacopoeia (where it is necessary). It is necessary to use only the standard reductions, names or codes.

Reception of materials and pharmaceutical products

5.7. At reception of the goods it is necessary to check up the received set on conformity to the order, and each container physically to verify, i.e. to check up
number of a set, type of a material (a pharmaceutical product) and its amount on conformity to a label.

5.8. It is necessary to check up uniformity of containers in a set and if necessary to divide the put goods under numbers of sets if some parties of the goods are put.

5.9. Each container is necessary for checking up on presence of possible pollution, infringements or damages, and suspicious containers or, in case of need, all set to send on quarantine with the purpose of the further investigation.

5.10. If necessary sampling should be carried out only specially trained and qualified personnel in strict conformity with written instructions. Containers from which tests get, should be accordingly marked.

5.11. After sampling the goods should be quarantined. The set should be isolated during all period of quarantine and the subsequent storage.

5.12. Materials and pharmaceutical products should remain on quarantine before reception of the official sanction to removal of quarantine or rejection.

5.13. It is necessary to arrange on prevention of use of the rejected materials and pharmaceutical production. This production should be kept separately till the moment of recycling or return to the supplier.

**Updating of stocks and the control**

5.14. It is necessary to carry out periodically the inventory of production, verifying records with the goods available.

5.15. At revealing discrepancies it is necessary to carry out investigation with the purpose of revealing inadvertent mistakes and-or incorrect holiday.

5.16. At the industrial enterprises containers with in part used materials or pharmaceutical products should be closed reliably and repeatedly to seal, to prevent defacement and-or pollution at the subsequent storage. Materials and products from open containers or in part used should be applied first of all.

5.17. Products in the damaged packing can be released only in the event that it is established, that quality of contents has not suffered. Whenever possible such facts
it is necessary to bring to the notice of the person responsible for quality assurance. All undertaken actions should be documentary fixed.

**Check on presence of the delayed and obsolete materials and products**

5.18. Stocks of production should be checked on a regular basis on presence of the delayed and obsolete materials and products. It is necessary to take necessary safety measures to not admit holiday of the delayed materials and pharmaceutical products.

**6. Return of the goods**

6.1. The returned goods, including withdrawn production, should pass the established procedure of return, and all records and reports should be kept.

6.2. The returned goods should be subjected to quarantine. To keep them together with other goods it is possible only under the decision officially persons. The given decision can be accepted on the basis of satisfactory results of reassessment of quality.

6.3. Any goods repeatedly released in the manipulation should be identified and registered documentary. The pharmaceutical preparations returned by patients in a drugstore, it is necessary to destroy.

**7. Sending and transportation**

7.1. At transportation of materials and pharmaceutical products it is necessary to care of preservation of integrity of the goods and about observance of conditions of storage.

7.2. It is necessary to show extra care at use of dry ice in cold circuits. Except for observance of usual security measures, it is necessary to keep up, that materials or products did not contact to dry ice as it can negatively be reflected in quality of production (for example, to result in freezing).

7.3. The temperature is recommended to use whenever possible devices for the control of such parameters, as, for example. Indications of devices are necessary for fixing with the purpose of the subsequent check.
7.4. Sending and transportation of materials and pharmaceutical products should be carried out only after reception of the order for delivery. Reception of the order and sending of the goods should be documentary fixed.

7.5. Sending should be organized and made documentary out in view of type of the ordered materials or pharmaceutical production and at observance of special precautions.

7.6. Packing should provide adequate protection against external influences and to be precisely marked with an indelible marker.

7.7. It is necessary to keep reports on sending of the goods where are specified:
   - date of shipment;
   - name and the address of the customer;
   - the description of production (the name, the medicinal form and force of action (where it is necessary), number of a set and quantity;
   - conditions of transportation and storage.

7.8. Reports should be easily accessible and be given by inquiry.

8. **A response of production**

8.1. It is necessary to develop the procedure allowing quickly and effectively to carry out a response of pharmaceutical products or materials if there are doubts in their quality or authentic data on their unsatisfactory quality.

   **Normal conditions of storage**

   Normal it is considered storage in a dry, well aired room at temperature 15-25°C or, depending on climatic conditions, up to 30°C. Extraneous smells, other sources of pollution and intensive light should be excluded.

   **The specific (certain) conditions of storage**

   Medical products which should be kept under specific conditions, demand corresponding instructions on storage. Deviations from instructions are supposed only for the short-term period (for example, during local transportations), if thus special conditions (for example, constant storage in a cold) are not stipulated separately.
It is recommended to use the following formulations of instructions on labels:

<table>
<thead>
<tr>
<th>It is specified on a label</th>
<th>Means</th>
</tr>
</thead>
<tbody>
<tr>
<td>To keep at temperature is not higher 30°C</td>
<td>From +2°C up to +30°C</td>
</tr>
<tr>
<td>To keep at temperature is not higher 25°C</td>
<td>From +2°C up to +25°C</td>
</tr>
<tr>
<td>To keep at temperature is not higher 15°C</td>
<td>From +2°C up to +15°C</td>
</tr>
<tr>
<td>To keep at temperature is not higher 8°C</td>
<td>From +2°C up to +8°C</td>
</tr>
<tr>
<td>To keep at temperature is not lower 8°C</td>
<td>From +8°C up to +25°C</td>
</tr>
<tr>
<td>Avoid damp</td>
<td>No more than 60 % humidity under normal conditions storages; to release to the patient in moistureproof packing</td>
</tr>
<tr>
<td>To protect from light</td>
<td>To release to the patient in light protect to packing</td>
</tr>
</tbody>
</table>

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Cycle of technical reports the CART, № 908, 2003 // www.who.int/medicines

MEDICINE CLASSIFICATION

Drugs are one of the profession most valuable tools. Drug include any substance or mixture of substance manufactured, sold or represented for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state or the symptoms thereof, in man or animal. Doctors prescribe drugs to treat or prevent many diseases. They relieve pain and tension and help the body function properly. The use of drugs helped millions of people to live longer and healthier. Medicines may be classified according to the different parameters. For example, according to the chemical structure, pharmacological activity and others. The type of classification depends on the aim of it’s users and the information they are need in.

The medicine Classification is needed, foremost, for systematization of the generous amount medicine and comfort of the use by information about them by the specialists of industry. Thus, creation of different classifications is carried out in
accordance from the concrete necessities of users: doctors, pharmacists, pharmacologists, chemists.

**Classification after an alphabet.** In basis of this classification principle of placing of the medicine names is fixed after an alphabet. This type of classification at drafting of reference books, the medicine (for example, list of basic medicines) lists, and also price-lists of commercial firms are most often used.

For example, they can be grouped according to their medicinal form, such as shown in the table 3 or they can be classified according to the way they are taken such as by swallowing, inhaling, or injection. Drugs are also be grouped according to their chemical structure, to the major beneficial effect they have on body.

**Types of medicines according to the basic systems of organism**

1. **For the gastrointestinal tract or digestive system**
   - **Upper digestive tract:** antacids, reflux suppressants, antiflatulents, antidopaminergics, proton pump inhibitors, H2-receptor antagonists, cytoprotectants, prostaglandin analogues
   - **Lower digestive tract:** laxatives, antispasmodics, antidiarrhoeals, bile acid sequestrants, opioids

2. **For the cardiovascular system**
   - **General:** beta-receptor blocker, calcium channel blockers, diuretics, cardiac glycosides, antiarrhythmics, nitrate, antianginals, vasoconstrictor, vasodilator, peripheral activator
   - **Affecting Blood pressure:** ACE inhibitors, angiotensin receptor blockers, alpha blocker
   - **Coagulation:** anticoagulant, heparin, antiplatelet drug, fibrinolytic, anti-hemophilic factor, haemostatic drugs
   - **Atherosclerosis/cholesterol agents:** hypolipidaemic agents, statins.

3. **For the central nervous system**
   - hypnotic; anaesthetics, antipsychotic, antidepressant (including tricyclic antidepressants, monoamine oxidase inhibitor, lithium salt, selective serotonin
reuptake inhibitor), anti-emetic, anticonvulsant and antiepileptic, anxiolytic, barbiturate, movement disorder drug, stimulant (including amphetamines), benzodiazepine, cyclopyrrolone, dopamine antagonist, antihistamine, cholinergic, anticholinergic, emetic, cannabinoids, 5-HT antagonist

4. For pain & consciousness (Analgesic drugs)

The main classes of painkillers are NSAIDs, opioids and various orphans such as paracetamol, tricyclic antidepressants and anticonvulsants.

5. For musculo-skeletal disorders

NSAIDs (including COX-2 selective inhibitors), muscle relaxant, neuromuscular drug anticholinesterase.

Biochemical classification

Biochemical drugs classification is proposed. Drugs are divided into 6 classes, according to their action on:
1) signal-transduction systems;
2) other components of plasmatic membranes;
3) intracellularly;
4) gene therapy;
5) extracellularly;
6) invasive agents.

Chemical Structure classification

Compounds are often classified according to their chemical structures. Although this is useful for medicinal chemists, it does not provide a meaningful classification scheme for categorizing drug effects. The structural formulas of medicine and their chemical properties are fixed in its basis. After this classification all medicinal matters divide into large groups: inorganic and organic nature. With the turn every group, depending on the structure, divides into sub-groups and etc.

Some compounds with similar chemical structures produce very similar biological effects (e.g., morphine, heroin), but others which belong to the same chemical class often produce much different effects (e.g., apomorphine, nalorphine).
Furthermore, compounds which differ in chemical structure often produce similar biological effects (e.g., amphetamine, cocaine).

**Pharmacological Activity classification**

This scheme classifies drugs according to their primary pharmacological activity. All compounds produced multiple effects, so what is considered the primary effect and what is considered the secondary effect varies as a function of reference point. Often the primary therapeutic use of a compound is considered its primary effect and thus used to classify it pharmacologically.

**ATC classification**

WHO's ATC codes provide a hierarchical classification of medicines by anatomical therapeutic and chemical classes. World Health organization record number code. A unique sequential number is assigned to each unique single component drug and to each multi-component drug. Eight digits are allotted to each such code, six to identify the active agent, and 2 to identify the salt, of single content drugs. Six digits are assigned to each unique combination of drugs in a dispensing unit. The six digit code is identified by W1, the 8 digit code by W2.

In the ATC classification system, drugs are divided into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutic properties. Drugs are classified into groups at 5 different levels.

1St level - At the broadest level, drugs are divided into one of the following fourteen anatomical groups. The first level of the code is based on a letter e.g. “B” for Blood and blood forming organs:

- a_ Alimentary tract & metabolism
- b_ Blood & blood forming organs
- c_ Cardiovascular system
- d_ Dermatologicals
- e_ Genito urinary system & sex hormones
- f_ Systemic hormonal preparations
Antiinfectives for systemic use
Antineoplastic & immunomodulating agents
Musculo-skeletal system
Nervous system
Antiparasitic products
Respiratory system
Sensory organs
Various

2nd level - is either a pharmacological or therapeutic subgroup (e.g., “B03” for Antianemic preparations) and indicates them by adding two arabic numbers begin with 01:
A01 – medicines used in stomatology.

3rd level - is a chemical or therapeutic or pharmacological subgroup and indicated with one Latin letter:
A02A – antacids.

4th level - is a chemical or therapeutic or pharmacological subgroup. This is the level used to count “number of different drugs” as it is the level which aggregates drugs just above their descriptive chemical substance. A count of an individual’s drugs at the fourth level of ATC gives the researcher a categorical option with which to stratify and then describe pharmaceutical users. It approximates a measure of comorbidity. The fourth level is indicated by one Latin letter:
A02AB – Aluminium compounds.

5th level - is the subgroup for the chemical substance. (international unpatented name of therapeutically active ingredient) and indicated again by two Arabic number:
A02AB02 – Algeldratum;
A02AB04 – Carbaldratum.

ATC classification is recommended by WHO for creation national list of medicines.

Medicine Classification
The Medicines Act 1968 defines three legal categories of medicines. These are:

- General sale medicines
- Pharmacy only medicines
- Prescription-only medicines

**General sale list medicines (GSL)** may be sold from a wide range of shops such as newsagents, supermarkets and petrol stations. Often, only a small pack size of the medicine may be sold. For example, the largest pack size of paracetamol that may be sold from a shop is 16 tablets whereas packs of 32 tablets may be sold from a pharmacy. Usually, only low, strengths of the medicine may be sold. For example, the highest strength of ibuprofen tablets that may be sold from a shop is 200mg whereas tablets containing 400mg may be sold from a pharmacy.

Restricted Medicines, also known as Pharmacist Only Medicines, are products that may only be sold by a pharmacist. **Pharmacist Only Medicines (P)** are only available for sale through pharmacies. Pharmacy medicines may only be sold from a pharmacy. A pharmacist must make or supervise the sale. Before being sold a pharmacy medicine, the person will usually be asked if he/she has any medical conditions and if you take any other medicines. This is to check that it is safe for you to take the pharmacy medicine.

**Prescription-only medicines (POM)** are those medicinal products that are need in prescription to be sold. Only POM may contain any controlled drug and the medicinal products for the parenteral administration.

**Controlled drugs**

Some prescription only medicines are further classified as Controlled drugs, for example, as morphine, pethidine and methadone. In some cases, these medicines may be misused or sold illegally, so there are stricter legal controls on their supply.

There are controls on:

- who may prescribe these medicines,
how the prescription is written,
how much may be prescribed, and
how the medicines are stored in the pharmacy.

Also, the pharmacist must make a record of the prescription in the controlled
drugs register. The controls are currently under review and are likely to be made even
stricter in the future.

Some medicines may be reclassified from Prescription only to Pharmacy or
from Pharmacy to General sale list. This can happen after several years, when it’s
known that the medicine is safe for most people to use. For example, aciclovir cream,
which can be used to treat cold sores, was first available as a Prescription only
medicine. After a few years, it was reclassified to a Pharmacy medicine and recently,
it has been reclassified again to a General sale list medicine.

Pharmacist Only Medicines as well as General sale medicines may be sold
without the prescription and are called over-the-counter drugs (OTC-medicines). The
OTC Medicines Guide is divided into main therapeutic categories, with associated
sub-categories. For example, the category Analgesia has five sub-categories -
headache, migraine, period pain, muscular pain (oral agents) and muscular pain
(topical agents).

Anybody doesn't need a prescription to buy OTC medicine. OTC is short for
over-the-counter. These are medicines somebody can buy without a prescription from
your doctor. Chances are, somebody has used OTC medicines many times to relieve
pain and treat symptoms of the common cold, the flu, and allergies. But like
prescription drugs, OTC medicines can also cause unwanted and sometimes
dangerous side effects. Before person buys an OTC medicine, it’s important to read
and thoroughly understand the information on the drug label. OTC medicines can
help person to feel better. But if they are taken the wrong way, they can actually
make feel worse. OTC medicines often do more than relieve aches, pains and itches.
Some can prevent diseases like tooth decay, cure diseases like athlete’s foot and, with
a doctor’s guidance, help manage recurring conditions like vaginal yeast infection, migraine and minor pain in arthritis.

Everybody should know the following things about each medicine:

- Name (generic name and brand name)
- Reason for taking it
- How much to take and how often to take it
- Possible side effects and what to do if you have them
- How long to continue taking it
- Special instructions (taking it at bedtime or with meals, etc.)

Table 3

<table>
<thead>
<tr>
<th>DRUGS</th>
<th>PRESCRIPTION</th>
<th>NON-PRESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>READY-MADE</td>
<td>EXTEMPOREOUS</td>
<td>READY-MADE</td>
</tr>
<tr>
<td>Tablets, capsules, pills, inhalation products, gels, powders, ointment, suppositories, liquids such as syrups, solutions, suspensions, mixtures, drops, tinctures and decoctions etc.</td>
<td>THINGS FOR MEDICAL CARE</td>
<td>PLANT DRUGS</td>
</tr>
<tr>
<td>thermometers, cups, hot-water bottles, bandages, cotton and gauze etc.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Technologists usually use the classification according to the medicinal form (table 4).

One more classification that is certainly used at chemists devides them for two groups: prescription and non-prescription drugs (table 3).

NONPRESCRIPTION drugs such as aspirin and some cough medicines are considered safe enough to be sold over the counter that is any drug or product not requiring a prescription for sale. PRESCRIPTION is an order from a practitioner authorizing the dispensing of a drug. Prescription drugs include antibiotics, barbiturates and certain tranquilizers. READY-MADE is a drug which is
manufactured at pharmaceutical factory. EXTEMPOROUS - a drug which is making under the prescription.

Table 4

<table>
<thead>
<tr>
<th>Medicinal forms</th>
<th>solid</th>
<th>soft</th>
<th>liquid</th>
<th>gas</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>tablets, capsules, pills, powders</td>
<td>gels, ointment</td>
<td>syrups, solutions, suspensions, drops, mixtures, tinctures and decoctions</td>
<td>inhalation products</td>
</tr>
</tbody>
</table>

**ORGANIZATION OF THE MEDICINE QUALITY CONTROL SYSTEM IN PHARMACY**

The level of pharmaceutical providing depends on correctly organized of medicine quality control system.

Result of properly constructed medicine quality control system are the prevention of diseases, physical inabilities and fatal cases owing to prevention of receipt of poor-quality medicines to the patient, a guarantee of efficiency and safety of medicines.

**Quality of a medicine** is a total combination of properties that allows a medicine to satisfy the requirements of consumers according to its purpose, and to correspond with the conditions established technological and the normative documentation (ND). The medicine should satisfy requirements of health protection for diagnostics, preventive measures and treatment of different diseases.

Properties of a medicine are:

- Efficiency;
- Safety;
- Conformity and the quantitative contents of components;
- Absence of impurity;
- Activity and stability of a chemical compound of a medicine;
- Stability storage;
- Cost.

Quality of a medicine is inherent in process of scientific research at stages of introduction of a medicine in practice and industrial production.

Further the medicine is subject to the control over high quality which is carried out in two directions:
- by an estimation of its quality;
- by warranting quality.

The estimation of quality of a medicine is an activity of official bodies which have the right to estimate it by inspection, supervision, the control, and accuracy of observance and performance requirements to quality by the industrial enterprises, drugstores, irrespective of an ownership pattern and a departmental belonging.

This work is carry out by State service of medicines and products of medical purpose, the State drug quality control inspection of Ministry Of Health Protection in Ukraine, and also its territorial divisions.

Warranting of quality of a medicine is an activity of the enterprises and establishments which produce and distribute the medicines, directed on providing of high quality of a medicine on the way from the manufacturer to the consumer.

The quality analysis of a medicine is carrying out laboratory research of medicine and auxiliary substances quality control according to the methods of the analysis stated in the normative documentation of Ukraine and definition of conformity of the checked up samples according to the requirements of the normative documentation.

Substandard (poor-quality) medicine is the preparation made by the legal manufacturer with correct marks but which as a result of absence of appropriate conditions of manufacture or transportation, or storage don’t correspond the established requirements of normative documents.
**The forged medicine** is a medicine which purposely and illegally supplied with a label it (is incorrectly marked), incorrectly indicating authenticity of a preparation and-or the manufacturer.

**Unregister medicine** is a medicine without the state registration in the State pharmacological center.

The International quality standards of pharmaceutical branch

According to the norms and rules accepted in the majority of the countries of EU, the USA, Canada – the enterprise - manufacturer should use the best efforts on creation of high quality production. This approach has been put in a basis of the document accepted by the European community – « the Global concept of legislative providing of quality of the goods and services in the European market »

**Main principles of this concept:**
1. Presence of obligatory quality system at the manufacturer
2. Check of products through test laboratories
3. Uniform system of an estimation of conformity of quality – certifications

For realization of the given concept the complex of standards which describe components and structure of such control system has been created, as well as the requirement to its elements, so-called standards of family 9000 which are accepted by the International organization of standardization.

ISO 9000 - is a complex of norms and requirements which are showed to manufacturers for providing of guaranteed quality of production and services.

ISO 9000 has recommendatory character and it is used by preparation of national standards of management. In case of acceptance by its national services of standardization, 9000 gets the double name – international and national. For today it is applied in more than 50 countries of the world, including Russia.

**The quality standards for pharmacy are:**
A) Good pharmaceutical practice
B) Good clinical practice
B) Good manufacture practice
The quality control system of medicine in the developed countries includes national bodies on registration, licensing and quality control. Providing of drug quality is reached due to observance of GMP requirements by the enterprises and manufacturers and regular inspection of manufacture by corresponding regular bodies.

The State drug quality control system of the medicines.

Legislative base.

The state control system of quality of pharmaceutical production represents the centralized structure of an economic complex of the country. Drug quality control system is the important condition of normal functioning of pharmaceutical branch.

Today the drug quality control system has three levels of formation:
- state (republican)
- regional
- level of the subject of business

The basic function of the given system is providing of the state control over the legislation, on manufacture, in sphere of export-import attitudes(relations), wholesale and retail realization.

Normative base of functioning of system are the Constitution of Ukraine, Decrees of the President, the Decision of the Cabinet of Ministers, orders of Ministry of Health and other regulating documents.

On state (republic) level the system of quality control is submitted:
- The president
- The cabinet of Ministers
- Ministry of Health
- Public service of medicines and products of medical purpose (Is engaged in questions of licensing, carrying out of accreditation of chemist's establishments)

- The state inspection of medicine quality control – which primary goal is realization of the state control over quality of medicines and products of medical purpose.

Powers of the State inspection are determined by Article 15 of the Law of Ukraine « About medicines » and other normative acts.

**Functions of the state inspection of medicine quality control:**

1. The control of observance of requirements Pharmacopoeia articles, industrial rules, the engineering specifications by the enterprises, the organizations, firms;

2. Realization of the preliminary and selective control over quality of medicines of the chemist's manufacture;

3. Providing of corrective measures of the infringements revealed at quality check of pharmaceutical production by the corresponding Ministries and their department;

4. Definition of quality of production at a disagreement between suppliers and consumers;

5. Certification and standardizations of preparations and products of chemist's manufacture;

   - The state Pharmacological center - engaged in development of requirements and carrying out of tests (preclinical and clinical) new pharmacological substances and medicines.

**At a regional level, the system is submitted:**

- Regional inspection of medicine quality control in the regional centers

They are the legal organisations having independent balance, the bank account, forms and a seal. Have 2 sources of financing: the state budget and self-supporting activity (the preregistration control over introduction of medicines in manufacture, etc.)
Subordinated laboratories of medicine quality control:

At a level of the subject of business (factories, pharmacies...) the monitoring system of quality is submitted by:
- Laboratories of drug quality control
- Checking technical departments at the enterprises
- Control-analytical service of drugstores (pharmacist)
- Institute «authorized person»

At each industrial enterprise there is a Checking technical department with the subordinate laboratory, each series of production made at the enterprise can abandon the enterprise only after the positive conclusion of Quality technical Department about conformity of the given series according to the requirements of the normative documentation.

Pharmaceutical production can be accepted for wholesale and retail realization only on the basis of the conclusion of Quality technical Department such as the Certificate of quality of a manufacturer.

The certificate of quality of the manufacturer is the document given by the manufacturer, guaranteeing conformity of a series of a medicine to the requirements established during its registration in Ukraine.

The entrance control

The entrance control (visual) – the control carried out by "the authorized person» who is responsible for quality of medicines.

«The authorized person» - the person having the higher or average pharmaceutical education, appointed by the director of the establishments on a post according to the order on establishment. He is responsible for the realization of entrance quality control of medicines, which are subject to retail, and wholesale realization.

The basic duties of the authorized person:
- Control of the accompanying documents of the medicine - waybills, with the indication of the name, a dosage, the medicinal form, № series, quantities(amounts), names of the manufacturer
- Registration of the conclusion of entrance drug quality control
- Conducting the register of medicines, which have arrived in order to have an opportunity to establish a source in case of receipt of the poor-quality or forged medicines
- Giving territorial inspection the data about revealed poor-quality medicines

**An entrance quality control includes the following actions:**

- Control of the license for the right of wholesale realization or manufacture of medicines at purchase of the goods;
- Realization of the visual control of all received medicines;
- Check of conformity of accompanying documents and medical goods by quantity(amount), a dosage, etc.;
- Stock-taking of the certificate of the quality given by the manufacturer on each party(set) of a medicine;

results of the entrance control can be:

- **positive** - provide the realization of a party(set) of the goods
- **negative** - provide writing up "the Act about the revealed defects" which is a basis for returning the goods to the manufacturer
- **doubtful** – provide sending the samples of medicines and their departure to the territorial inspection for laboratory researches.

The order of carrying out of entrance quality control at wholesale realization is the same as well as at retail.

**The organization of intrachemist's quality control of medicines**

One of elements of system of warranting of medicines quality is intrachemist's quality control.
Intrachemist's quality control is an industrial activity which is directed on the prevention (warning) of the poor-quality of receipt and forged medicines from a drugstore to the patient, and also the prevention of wrong storage of medicines in chemist's establishments and pharmaceutical firms. It includes a complex of warning measures, carrying out of obligatory and selective kinds of quality control of medicines prepared in a drugstore.

If the chemist shop has the production function – preparation of medicines under individual recipes and requirements, it should have properly organized control system of quality.

First of all, it is necessary, that the full complex of measures preventing occurrence poor-quality medicines by manufacture was carried out, namely:

- observance of rules and norms of a sanitary-and-hygienic and epidemiological mode;
- providing of serviceability and accuracy of the equipment;
- providing of rules and conditions of storage medicines according to their physical and chemical properties;
- control of recipes and hospital requirements which come in a drugstore;
- observance of manufacturing techniques of medicines;
- preparation of auxiliary materials, utensils according to the requirements showed to them.

Second, functions of the control-analytical laboratories include realization of the selective control of medicinal forms of chemist's manufacture.

The drugstores has a post of the pharmacist – analitic which should held all kinds of intrachemist's quality control, and even at absence of this post, the head is obliged to provide quality control of medicines in full according to documents.

Functions of the pharmacist - analytics:

- Realization of all kinds of intrachemist's quality control;
- The control over observance of technology of preparing of medicines, rules of storage in a drugstore;
- Consultation on questions of storage, technology of preparation and quality control;
- Conducting registration forms under the established forms.

To the intrachemist's control are exposed:

- all medicines prepared in a drugstore;
- intrachemist's preparations;
- solutions - concentrates;
- semifinished items;
- water cleaned and sterile.

There are 6 kinds of the intrachemist's control. They can be divided on:

- obligatory – each preparation made in conditions of a drugstore is exposed to the control,
- selective forms – are carried out depending on different factors (age of the patient, the medicinal form, structure of a preparation).

**OBLIGATORY kinds of the control**

**The written control** – consists in check of conformity of records in the passport of written control prescription in the recipe, correctness of the made calculations.

**Organoelectrical control** – is carried out as check of appearance of the medicinal form, color, smell, uniformity, absence of mechanical inclusions.

**The control over realisation** – provides conformity:

- packings of a medicine to the physical and chemical properties
- registrations of a preparation
- dosages of medicines of the list A and age of the patient
- numbers on the recipe and numbers on the label
- surnames of the patient on the receipt and on the medicine

**The SELECTIVE forms of the control:**
The polling (oral) control is carried out after manufacturing by the pharmacist no more than 5 medicinal forms. The pharmacist who is carrying out the control, calls the first component, and the assistant should call components of the medicinal form and their amounts.

The physical control – is carried out by check of a weight or volume of the medicinal form, quantity(amount) and weight of separate components, and also by means of quality control of packing.

The subject to check:

- 3-5 units of packing or preparations in each series of packing or preparation
- sterile medicinal forms

The chemical control includes the definition of authenticity (the qualitative analysis) and the quantitative contents of the medicines included in the medicinal form.

The chemical control is obligatory for the following medicinal forms:

- Solutions for injections;
- Eye drops and the ointments containing narcotic, strong, poisonous substances;
- Medicinal forms for newborns;
- Solutions of an acid for internal application;
- Concentrates, the semifinished items prepared in a drugstore;
- Stabilizers, the buffer solutions used for manufacturing of injection solutions;
- Series of intrachemist's medicines.

The qualitative chemical control is carried out for the following forms:

1. Water cleared from each cylinder daily.
2. Medicines, concentrates, the semifinished items acting in assistant their rooms of storage.
3. Concentrates, the semifinished items coming from a warehouse – in case of doubt.

Estimation of quality of medicines

There are 2 terms of quality estimation of the made medicines:

1. "Satisfactory"
2. "Unsatisfactory"

2.1 « It is unsatisfactory on conformity »:
- absence of the attributed component;
- presence of not registered component;
- use of preparation - analogue without corresponding instructions (indications) of the doctor in the recipe;

2.2 « It is unsatisfactory on physical parameters »:
- bad mixing or grinding of components;
- impurity of a solution with mechanical inclusions;
- excess of norms of a deviation of separate dozes, lump (volume).

AUTOMATED INFORMATION RETRIEVAL SYSTEM IN PHARMACY

The modern trend of informing about drugs at various levels of management is automatization. The basis of the automated methods of information are information retrieval systems, which is the sum of the database domain, a set of software applications and hardware for their implementation. As the last used personal computers (PCs).

The levels of AIRS are divided into global (international), universities (national), average (branch) and lower (local) - at the institutional level.

AIRS is an example of a local information system "Farm Info" developed in 1996 at the Department of Pharmacology, National university of pharmacy. The basis of building a database incorporated a "passport" of medicine, which includes information on 37 indicators, the most important to characterize it: INN, trade name,
manufacturer, medicinal form, dosage, storage conditions, the data for registration in Ukraine, composition, sources of information on this preparation, the order of release, origin, etc. The system uses a classification of Mashkovsky, Vidal, with some clarifications and changes. The system includes a powerful query builder that allows to fully implement any request for information on the information contained in its database. The system is "open", it means allows you to make any changes to the database, completely Russified, performed in a networked version (designed for three levels of users). The system is designed for storage, processing information about the medicine and providing the user with this information in the form of reports. With the "Farm-Info" you can define synonyms or equivalents of medicine, its pharmacological group, as well as to identify the manufacturer, form, dosage, composition (in the case of combined drugs) and other information.