National University of Pharmacy

ORGANIZATION OF PHARMACEUTICAL PROVIDING OF THE POPULATION

Textbook
for university students

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The basic aspects of the management, the organization and the regulation of pharmaceutical providing population at the macro- and micro- levels in terms of wholesale and retail sale of pharmaceutical goods and devices, manufacturing medicines in pharmacies and quality assurance of medicines have been considered in the book.

The textbook is intended for students of pharmacy universities, faculties and also can be useful for practical pharmacy staff (employees).

CONTENT

ACRONYMS

ASHP - the American Society of Health-System Pharmacists

APhA - the American Pharmacists Association

CPJE - California Pharmacist Jurisprudence Examination

FIP - International Pharmaceutical Federation

GCP - Good Clinical Practice

GDP - Good Distribution Practice

GLP - Good Laboratory Practice

GMP - Good Manufacturing Practice

GPP - Good Pharmaceutical Practice

GPPP - Good Pharmaceutical Procurement Practice

GSP - Good Storage Practice

GSL - General Sales List medicines

INN - International non-patent name

ICC - International Chamber of Commerce

ICH - International Conference on Harmonisation

IFPMA - International Federation of Pharmaceutical Manufacturers Associations

INN - International Nonproprietary Name

ISO - International Organization for Standardization

NABPLEX - National Association of Boards of Pharmacy Licensing Examination

NAPRA - National Association of Pharmacy Regulatory Authorities

NDP - National Drug Policies

OECD - The Organisation for Economic Cooperation and Development

PEBC - Pharmacy Examining Board of Canada

Pharm. D. - the Doctor of Pharmacy

SPT - Structured Practical Training

VMI - Voluntarily medical insurance

WHO - The World health organization

WHA - World Health Assembly

Preface

The principal aim of this book is to provide an essential reference on organization of the Pharmacy Practice for pharmaceutical students. As such, it provides an overview of the major topics in organization and regulation of the pharmaceutical activity encountered by such students, in a practical, clear and succinct manner. The book introduces the material devoted to the international approaches in the organization of the state management and control system of the pharmaceutical activity by implementation of the National Drug Policy, International standarts of Good Practice, state regulation in process of licensing and medicine quality control and etc. The book is organized in 10 chapters. Every chapter has the questions to check understanding. All the questions set can be answered by students who have worked through the text to the chapter concerned.

As a text aimed at 4^{th} year Pharmacy students, it is not intended as an exhaustive reference text for each topic covered; rather, it should be considered as a starting point for further study, facilitated by regular signposting and referencing to the many excellent advanced texts available.

Students are strongly encouraged to pursue such directions as required, and as their overall level of understanding and ability develops.

The rapidly changing nature of the profession and the unfamiliar terminology and acronyms that are widely used often present barriers to students. That’s why this book also provides a list of acronyms and a glossary of common terms used in the discipline, which can be used either as the book is read as a whole, or as a companion text during the study of other texts on Pharmacy Practice.

Chapter 1. INTRODUCTION INTO PHARMACY PRACTICE

1.1. The practice of pharmacy

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

The medical aid either in policlinics or in hospital and different kinds of prophylaxes 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.

There are two levels of management in all branches of industry: macro- and micro economics. Macroeconomics: The study of aggregate behavior. How consumers, businesses, and society choose. What determines the level of output that our economy chooses?

Microeconomics. An emphasis on individual markets in the economics, i.e., an examination of price-output behavior in purely competitive, oligopolistic, monopolistically competitive, and monopolistic markets.

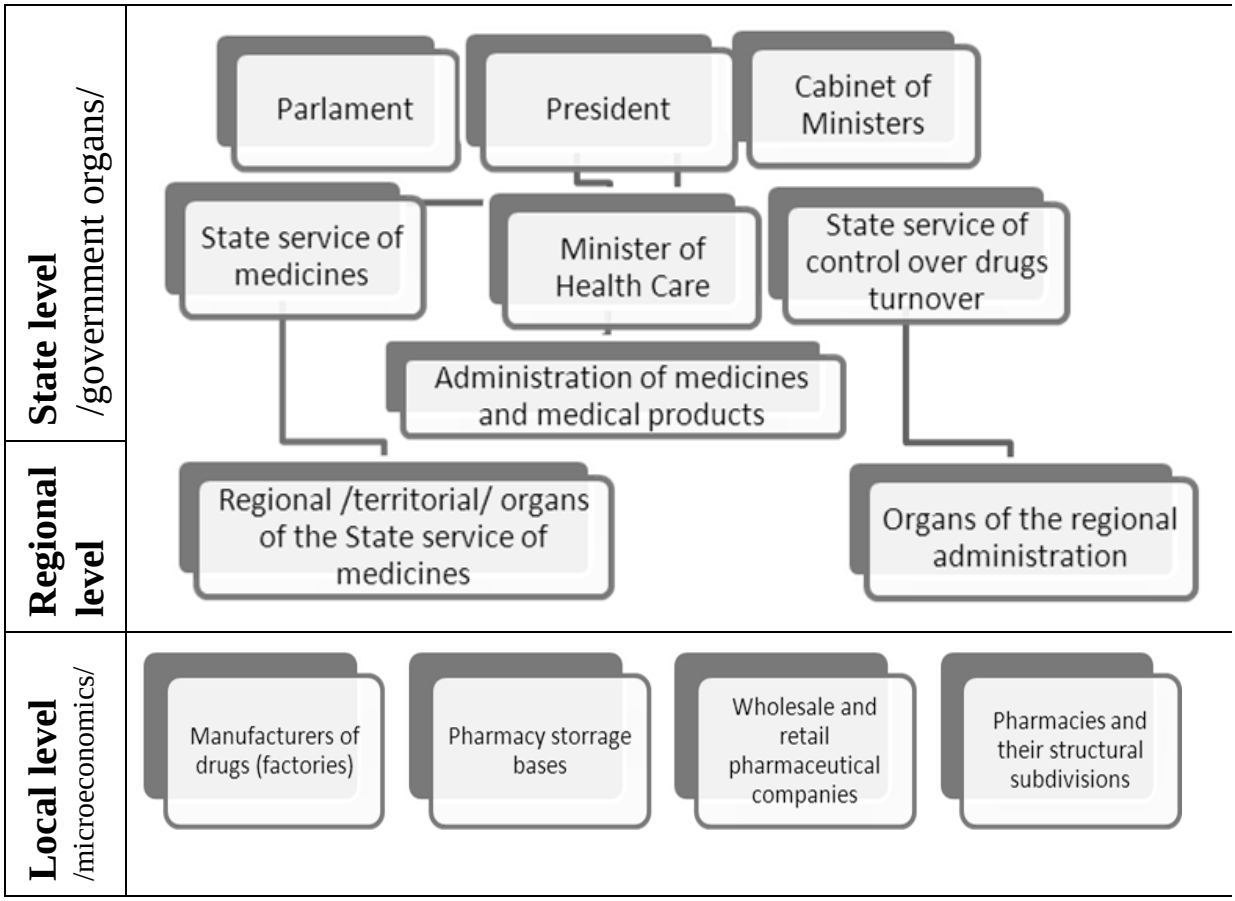
In pharmaceutical sphere macroeconomics investigates and solves following tasks on the state level:

1. Practically all the government guarantees the receiving of the pharmaceutical aids for the population. The principles of health are reflected in the Medical Care Law and the Constitution of the state and others.
2. The uniting of medical and pharmaceutical aids defenite as a correlation between doctors and pharmacists (9,5-10:1).

3. The principle of the chemists' development and location are usially described in the special documents. For example, the number of people served by one chemists' are: 10 – 12 thousands in USA, 3 – 4 thousands in England and France, 7 thousand in Austria etc. The different normatives and requirements can be determine in legal acts. (For example, the minimum square of the chemists' must be 70 sq. m.)
4. The state requirements to the drugs manufacture and distribution usually based on international norms and conventions.
5. Price policy of the state

Microeconomics investigates the tasks belong to the concrete enterprise, for example, chemists', pharmaceutical factory, laboratory.

The organizational structure of pharmaceutical industry is shown at scheme 1.1.



Scheme 1.1. Government management of the pharmaceutical industry

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.

Thus, **pharmacy** is the art and science of dispensing and preparing medication and providing drug-related information to the public. **Pharmacist** is an individual who is educated and licensed to dispense drugs and to provide drug information.

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.

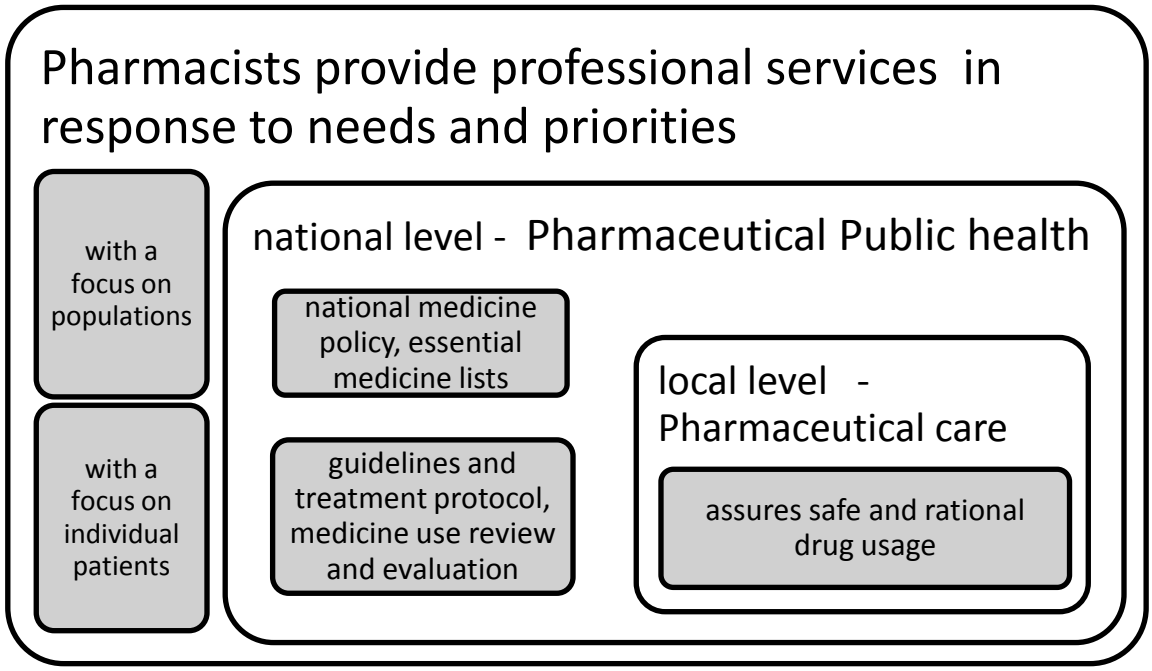
Pharmacy (from the Greek φάρμακον 'pharmakon' = drug) is the health profession that links the health sciences with the chemical sciences, and it is charged with ensuring the safe and effective use of pharmaceutical drugs.

The word pharmacy is derived from its root word pharma which was a term used since the 1400–1600s. In addition to pharma responsibilities, the pharma offered general medical advice and a range of services that are now performed solely by other specialist practitioners, such as surgery and midwifery. The pharma (as it was referred to) often operated through a retail shop which, in addition to ingredients for medicines, sold tobacco and patent medicines. The pharmas also used many other herbs not listed.

1.2. Role of a Pharmacist in Health Care System

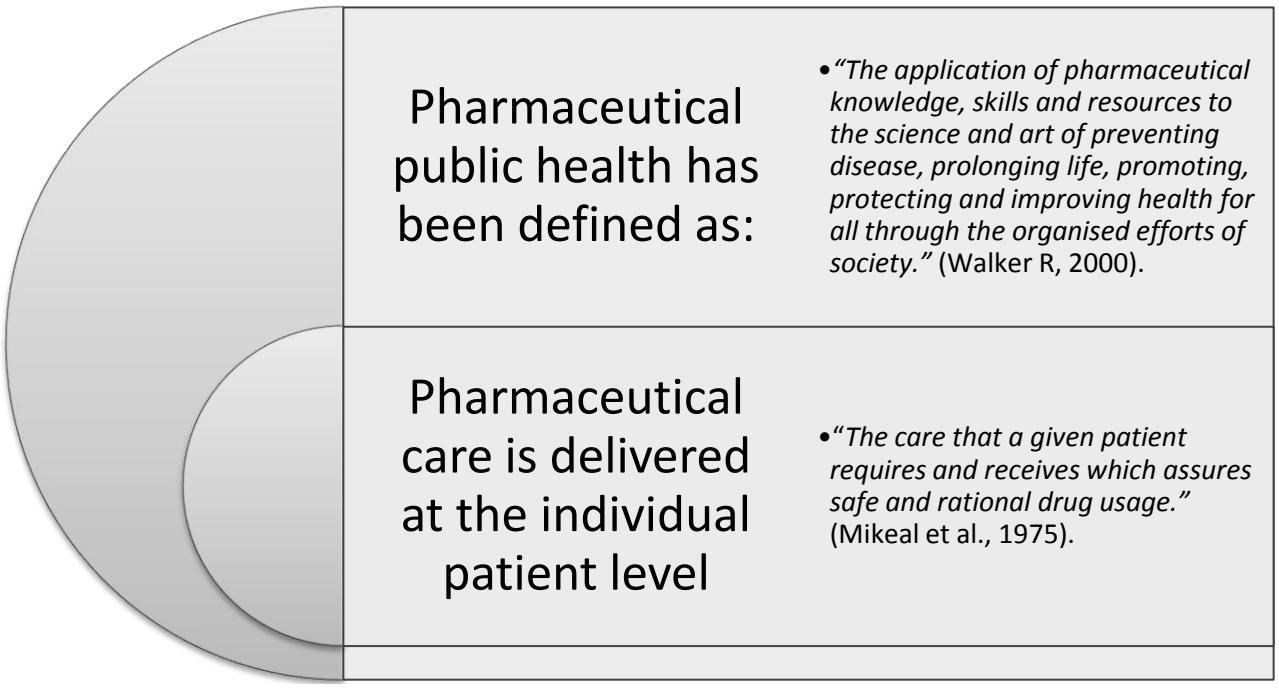
The scope of pharmacy practice includes more traditional roles such as compounding and dispensing medications, and it also includes more modern services related to health care, including clinical services, reviewing medications for safety and efficacy, and providing drug information. Pharmacists, therefore, are the experts on drug therapy and are the primary health professionals who optimize medication use to provide patients with positive health outcomes.

Today's pharmacists are highly respected as the medication management experts of the health care team. They collaborate with patients, their families and other health care providers to benefit the health of the population. Pharmacists provide professional services in a variety of settings in response to local, national and international needs and priorities, with a focus on populations and/or individual patients. Pharmaceutical public health includes services to populations, such as local guidelines and treatment protocols, medicine use review and evaluation, national medicine policies and essential medicines lists, pharmacovigilance, needs assessment and pharmaco-epidemiology.



Scheme 1.2. The priorities and needs of the pharmaceutical services

Pharmacists play a vital role in health care system through the medicine and information they provide (Scheme 1.3). While responsibilities vary among the different areas of pharmacy practice, the bottom line is that Pharmacists help patients get well. Pharmacist responsibilities include a range of care for patients, from dispensing medications to monitoring patient health and progress to maximize their response to the medication. Pharmacists educate consumers and patients on the use of prescriptions and over-the-counter medications, and advice physicians, nurses, and other health professionals on drug selection and utility.



Scheme 1.3. The approaches of pharmaceutical public health and pharmaceutical care

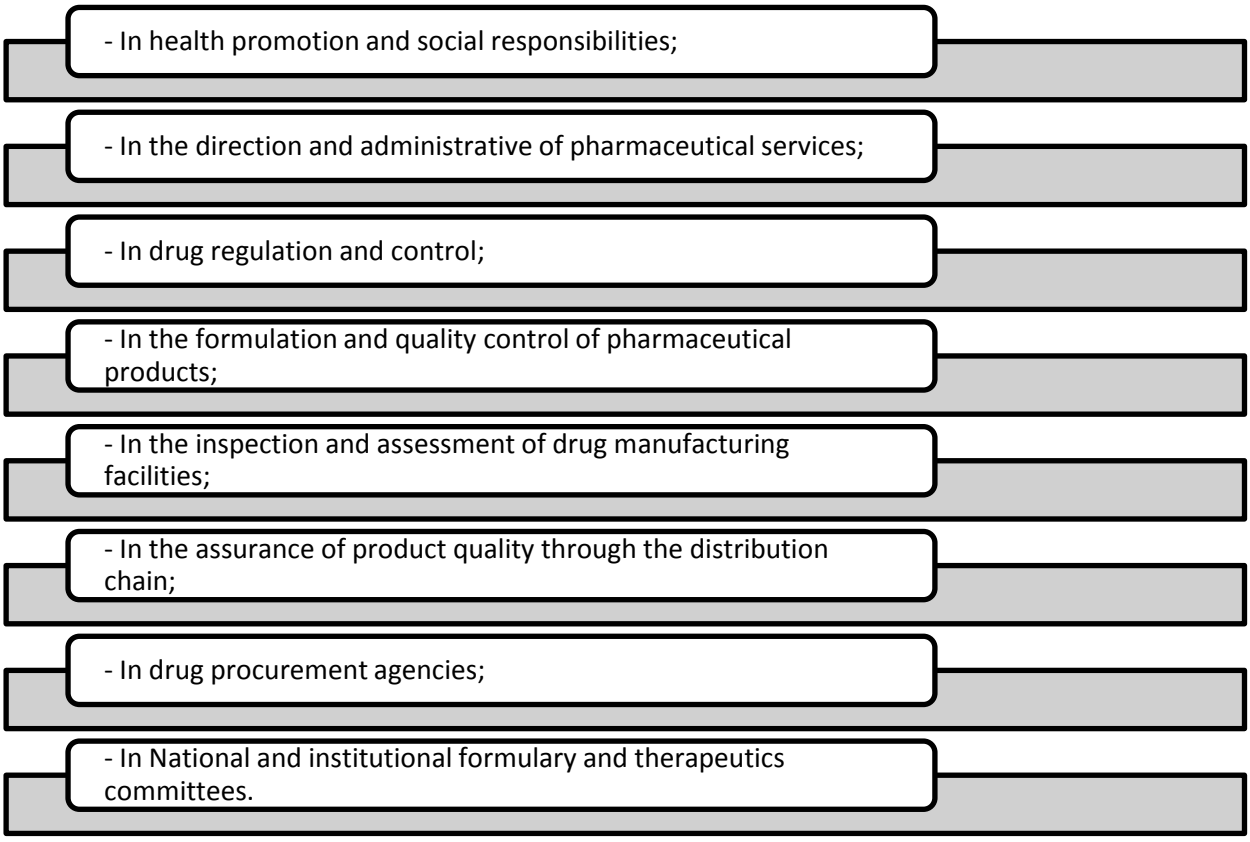
The principal goal of pharmaceutical care is to achieve positive outcomes from the use of medication which improves patients' quality of life with minimum risk. Pharmacists strive to

- Cure disease;
- Eliminate or reduce symptoms;
- Arrest or slow a disease process;
- Prevent disease;

- Diagnose disease;
- Alter physiological processes for desirable result in the patient's health.

Pharmacists also provide expertise about the composition of drugs, including their chemical, biological, and physical properties and their manufacture and use. They ensure drug purity and strength and make sure that drugs do not interact in a harmful way. Pharmacists are drug experts ultimately concerned about their patients' health and wellness.

The World health organization (WHO) report on "The role of the Pharmacist in the health care system" states that the competences of the Pharmacist is already proven and control (Scheme 1.4).



Scheme 1.4. The Pharmacist competences that are already proven and control (according to WHO report on "The role of the Pharmacist in the health care system")

In these activities, the pharmacist serves as a member of a multidisciplinary team rather than in an autonomous capacity; but in any particular country the profession can only be an efficiently organized element of the health care system

when it has gained representation within the senior ranks of administration in both government and industry. The basic functions of the Pharmacist in the health care system depend on the kinds of activity and are shown lower.

In drug regulation and control:

A Pharmacist in government drug regulatory affair department plays his role by regulating the quality of medications, price of the medications, applying the ethics and law about medications and industries.

In the formulation and quality control of pharmaceutical products:

The formulation of any medication is only depended on Pharmacist. It is one of the important roles of a Pharmacist. The physical, chemical and biological quality of a pharmaceutical product intended for administration to patients in the home must be of the highest quality attainable. This quality must be built in to the product in each step of the aseptic compounding process, that is, in the starting components, the design and operation of the compounding facilities, the control of the environment and the qualifications of operators all contribute to the final quality of the product, either in a positive or negative manner. Therefore, the control of quality is a continuous process through out the compounding of the product. Testing of the finished product can only confirm the quality built in to the product during its preparation. Here only a Pharmacist can play his role.

In the inspection and assessment of drug manufacturing facilities:

The another important duty of a Pharmacist (by joining the government testing laboratory and medicine regulatory service) is inspect the pharmaceutical industries, their environment, quality of medications, facilities and assesses the medications.

In the assurance of product quality through the distribution chain:

Distribution of medication is two types—

1.From industry to market

2.From hospital to the patient (through prescription)

From industry to market: -

After produced, before sending to the market ensuring the quality of pharmaceutical products is must, because it is directly related with life. Here only a Pharmacist plays a significant role.

From hospital to the patient (through prescription): -

The medication distribution system in hospitals is very complex and involves in several health care professionals. The usual flow is physician prescribes, Pharmacist dispenses and nurses administer medication. Here the Pharmacist who dispenses, has the right to change the medicine which is prescribed by the physician to ensure the quality of that medicine.

In drug procurement agencies:

The work of drug procurement agencies is to supply the medication and find out the possible customer in home and abroad. Here a Pharmacist plays a great role.

In national and intuitional formulary and therapeutics committees:

During recent years, with the development of the clinical pharmacy movement, a number of clinical Pharmacists on the staff of some departments have developed expertise in specific therapeutic specially areas. Therefore, it was a logical development under the pharmacy and therapeutics committee. The formulary system has attempted to outline the scientific data on a medication, including its toxicities, untoward side effects, safety profile and beneficial effects- has been a controversial method of appraising medication therapy. All these are provided by a formulary committee of a nation and this formulary committee is constructed by the Pharmacists. Except these a Pharmacist has important role to play as an Academic Pharmacist, Chain Drug Store Pharmacist, Compounding Pharmacist, Critical Care Pharmacist, Drug Information Specialist, Grocery Chain Pharmacist, Home Care Pharmacist, Hospice Pharmacist, Hospital Staff Pharmacist, Infectious Disease.

Pharmacists distribute prescription drugs to individuals. They also advise their patients, physicians, and other health practitioners on the selection, dosages, interactions, and side effects of medications, as well as monitor the health and

progress of those patients to ensure that they are using their medications safely and effectively. Compounding—the actual mixing of ingredients to form medications—is a small part of a pharmacist's practice, because most medicines are produced by pharmaceutical companies in standard dosages and drug delivery forms. Most pharmacists work in a community setting, such as a retail drugstore, or in a healthcare facility, such as a hospital.

Pharmacists in community pharmacies dispense medications, counsel patients on the use of prescription and over-the-counter medications, and advise physicians about medication therapy. They also advise patients about general health topics, such as diet, exercise, and stress management, and provide information on products, such as durable medical equipment or home healthcare supplies. In addition, they often complete third-party insurance forms and other paperwork. Those who own or manage community pharmacies may sell non-health-related merchandise, hire and supervise personnel, and oversee the general operation of the pharmacy. Some community pharmacists provide specialized services to help patients with conditions such as diabetes, asthma, smoking cessation, or high blood pressure. Some pharmacists are trained to administer vaccinations.

Pharmacists in healthcare facilities dispense medications and advise the medical staff on the selection and effects of drugs. They may make sterile solutions to be administered intravenously. They also plan, monitor, and evaluate drug programs or regimens. They may counsel hospitalized patients on the use of drugs before the patients are discharged.

Some pharmacists specialize in specific drug therapy areas, such as intravenous nutrition support, oncology (cancer), nuclear pharmacy (used for chemotherapy), geriatric pharmacy, and psychiatric pharmacy (the use of drugs to treat mental disorders).

Most pharmacists keep confidential computerized records of patients' drug therapies to prevent harmful drug interactions. Pharmacists are responsible for the accuracy of every prescription that is filled, but they often rely upon pharmacy

technicians to assist them in the dispensing medications. Thus, the pharmacist may delegate prescription-filling and administrative tasks and supervise their completion. Pharmacists also frequently oversee pharmacy students serving as interns.

Some pharmacists are involved in research for pharmaceutical manufacturers, developing new drugs and testing their effects. Others work in marketing or sales, providing clients with expertise on the use, effectiveness, and possible side effects of drugs. Some pharmacists work for health insurance companies, developing pharmacy benefit packages and carrying out cost-benefit analyses on certain drugs. Other pharmacists work for the government, managed care organizations, public healthcare services, or the armed services. Finally, some pharmacists are employed full time or part time as college faculty, teaching classes and performing research in a wide range of areas.

Work environment. Pharmacists work in clean, well-lighted, and well-ventilated areas. Many pharmacists spend most of their workday on their feet. When working with sterile or dangerous pharmaceutical products, pharmacists wear gloves, masks, and other protective equipment.

1.3. Historical aspects of the pharmacist role changing

The basic international events and guidelines influence on pharmacy practice

In the last quarter century, pharmacy has expanded its role within healthcare 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. The pharmacy profession has expanded significantly in terms of professional services delivery and now has been recognized as an important profession in the multidisciplinary provision of health care. In contrast to the situation in developed countries, pharmacists in developing countries are still underutilized and their role as health care professionals is not deemed important by either the community or other health care providers. The World Health Organization convened

a meeting of a consultative group on the role of the pharmacist in the health care system, in New Delhi, at the WHO Regional Office for South-East Asia, from 13-16 December 1988.

Medicinal therapy is the most frequently used form of treatment intervention in any health practice setting. Its use has grown dramatically as the population has aged, the prevalence of chronic disease has increased, new infectious diseases have emerged and the range of effective medications has broadened. In addition, more and more so-called "life-style medicines" – treatments for ailments like baldness, dry skin, wrinkles or erectile dysfunction – are being marketed.

Increasingly medicines can be purchased in new settings, and are handled by non-pharmacists. Compounding has been largely replaced by the commercial manufacture of nearly all formulations. Medicines can be bought in supermarkets, in drug stores or at markets. They can also be obtained by mail order or over the Internet in some countries; they are sold by medical practitioners and dispensed by computerized dispensing machines.

Professions exist to serve society. Hence the mission of the pharmacy profession must address the needs of society and individual patients. At one time, the acts of deciding on drug therapy and implementing it were relatively simple, safe and inexpensive. The physician prescribed and the pharmacist dispensed. However, there is substantial evidence to show that the traditional method of prescribing and dispensing medication is no longer appropriate to ensure safety, effectiveness and adherence to drug therapy. The consequences of medicine-related errors are costly in terms of hospitalizations, physician visits, laboratory tests and remedial therapy. In developed countries, 4%–10% of all hospital inpatients experience an adverse drug reaction – mainly due to the use of multiple drug therapy, especially in the elderly and patients with chronic diseases. In the USA, for example, it is the 4th–6th leading cause of death and is estimated to cost up to US$130 billion a year. Elsewhere, in the UK it accounted for £466 million (over US$812 million) in 2004.

In 1998, FIP published a Statement of Professional Standards on Medication Errors Associated with Prescribed Medication which aims to define the term "medication error" and to suggest a standard nomenclature to categorize such errors and their severity. The Statement also makes recommendations to members of the health care delivery system designed to improve safety in the manufacturing, ordering, labelling, dispensing, administration and use of medicines.

While appropriate drug therapy is safer and more cost-effective than other treatment alternatives, there is no doubt that the personal and economic consequences of inappropriate drug therapy are enormous. It is important for society to be assured that spending on pharmaceuticals represents good value for money. In view of their extensive academic background and their traditional role in preparing and providing medicines and informing patients about their use, pharmacists are well positioned to assume responsibility for the management of drug therapy.

The accountability of health professionals for their actions is another major issue in health care provision. In the traditional relationship between the doctor as prescriber and the pharmacist as dispenser, the prescriber was accountable for the results of pharmacotherapy. That situation is changing in rapidly evolving health systems. The practice of pharmaceutical care assumes the pharmacist to be responsible for patients under their care, and society will not only accept that assumption but hold the profession to it.

At the same time, other professions such as medical doctors, nurses and medical and pharmacy assistants also acquire competence and feel confident to function as drug therapy managers. In some countries they are moving aggressively to do so. Pharmacy students and practitioners must be educated to assume the responsibility for managing drug therapy, so that they can maintain and expand their position in the health care system and are compensated for their role in providing pharmaceutical care.

Dispensing is, and must remain, a responsibility of the pharmacy profession. While fewer pharmacists may be actually engaged in dispensing medication,

predominantly in rural areas, more pharmacists will be managing the dispensing process and assuming responsibility for its quality and outcomes. While change may generate potential threats, it can also open up immense opportunities.

The pharmacy profession has a responsibility to identify new opportunities for pharmacy practice in a changing health sector context, to assess and to test them, and to demonstrate their ability to implement them successfully.

In 1975, the World Health Assembly in resolution WHA28.66 requested WHO to develop means to assist Member States in formulating national drug policies. It also urged WHO to assist countries in implementing strategies, such as the selection of essential drugs and appropriate procurement of quality drugs based on health needs, and in providing education and training in various elements of pharmaceutical programmes. This resolution was followed by a series of events that marked the evolution of country drug programmes with the assistance of WHO.

The first WHO Model List of Essential Drugs was published in 1977. A year later the WHO/UNICEF Conference on Primary Health Care at Alma-Ata included access to essential drugs as one of the eight elements of primary health care. In 1979, the WHO Action Programme on Essential Drugs was established. Another landmark in promoting strategies to improve the pharmaceutical situation in countries was the 1985 Conference of Experts on Rational Use of Drugs in Nairobi. The following year's World Health Assembly adopted resolutions that reflected the Conference recommendations on promoting rational use. Also in 1986, a WHO Expert Committee on National Drug Policies met to develop practical guidance for Member States, published as Guidelines for developing national drug policies. This publication has proved very useful over the years.

The efforts of countries, WHO and other agencies have had a considerable impact.

The number of people with access to essential drugs has grown from roughly 2,100 million in 1977 to an estimated 3,800 million in 1999. By 1999, 66 countries had formulated or updated a national drug policy within the previous 10 years,

compared with 14 countries in 1989. By the end of 1999, 156 WHO Member States had a national essential drugs list; 127 of the lists had been revised within the previous five years.

Nevertheless, problems of access to quality drugs and rational use persist. Although few hard data are available, it is likely that in the poorest parts of Africa and Asia more than half the population still lacks access to essential drugs. And there are new challenges that may have an impact on access, such as the expansion of the private sector's role in pharmaceuticals, health sector reforms and the effects of globalization. The changing pattern of diseases, antimicrobial resistance and emerging new diseases are other factors. Particularly important is the current trend of governments to reduce health care spending because of inadequate resources, despite increasing health needs.

After a decade, and with new problems to be addressed, there was a clear need to revise the 1988 guidelines. The Expert Committee on National Drug Policies met in 1995 to review the current pharmaceutical situation and to start the updating process. Their deliberations resulted in a report that became the basis of the NDP. These updated guidelines focus on the national drug policy process, strategies and options which can be used by Member States and organizations active in the pharmaceutical sector. Each policy component is discussed, with a focus on current problems and new challenges. And each chapter presents strategies and practical approaches that can be used to improve the situation. All chapters include references to publications that provide additional technical and practical details.

In 1990, Hepler and Strand defined a new way to look at the responsibilities of the pharmacist and pharmacy services, applying the term "pharmaceutical care" to this new concept of pharmacists' services. Over the course of more than a decade, pharmacists have worked to develop pharmaceutical care practices. Defined as practice in 1997: Pharmaceutical Care is a patient-centered practice in which the practitioner assumes responsibility for a patient's drug-related needs and is held accountable for this commitment.

The first WHO Consultative Groups on the Role of the Pharmacist met in New Delhi in 1988 and in Tokyo in 1993.

Table 1.1.

The basic international event influence on pharmacy practice

The year	The event
1975	the World Health Assembly in resolution WHA28.66 requested WHO to develop means to assist Member States in formulating national drug policies
1977	The first WHO Model List of Essential Drugs was published
1979	the WHO Action Programme on Essential Drugs was established
1985	World Health Assembly adopted resolutions that reflected the Conference recommendations on promoting rational use
1986	WHO Expert Committee on National Drug published as Guidelines for developing national drug policies
1988	The first WHO Consultative Groups on the Role of the Pharmacist met in New Delhi
1990	Hepler and Strand defined a new way to look at the responsibilities of the pharmacist and pharmacy services, applying the term "pharmaceutical care"
1993	The International Pharmaceutical Federation first adopted the guidelines for Good Pharmaceutical Practice
1993	The second WHO Consultative Groups on the Role of the Pharmacist met in Tokyo
1995	The Expert Committee on National Drug Policies deliberations resulted in a report that became the basis of the NDP
1997	The third WHO consultative groups on the role of the pharmacist met in Vancouver
1997	Pharmaceutical care defined as practice
1998	FIP published a Statement of Professional Standards on Medication Errors Associated with Prescribed Medication
1998	The fourth WHO consultative groups on the role of the pharmacist met in The Hague
1998	“GPP in Developing Countries – Guidelines for Implementation”, was endorsed by the FIP CPS Executive Committee
2000	The concept of the “seven-star pharmacist” was introduced by WHO and taken up by FIP

In 1994, the 47th World Health Assembly called for the development and implementation of national medicines policies aimed at improving access to and rational use of medicines. National medicines policies, which have been developed in over 100 WHO Member States, provide a framework for good pharmaceutical practice. The WHO Revised Drug Strategy relating to the role of the pharmacist was also addressed in the 1994 resolution of the World Health Assembly.

This resolution recognizes the key role of pharmacists in public health, including the use of medicines. It emphasizes their responsibility to provide informed and objective advice on medicines and their use, to promote the concept of pharmaceutical care, and to participate actively in illness prevention and health promotion.

The third and fourth WHO consultative groups on the role of the pharmacist met in Vancouver in 1997 and in The Hague in 1998.

Other documents on good pharmaceutical practice include the WHO document "Good Pharmacy Practice (GPP) in Community and Hospital Pharmacy Settings" and the FIP documents "Guidelines for Good Pharmacy Practice" of 1993, revised in 1997, and "Good Pharmacy Practice in Developing Countries: Recommendations for stepwise implementation."

FIP has issued statements on professional standards for continuing professional development, good pharmacy education practice and pharmaceutical care.

Although many countries have already established their own good practice guidelines, the levels of knowledge about them, the ways in which they are used and monitored, and the ways in which practitioners learn how to apply them vary tremendously.

In 1993 the International Pharmaceutical Federation first adopted the guidelines for Good Pharmaceutical Practice. Conscious of the need to help developing countries achieve GPP, the FIP Community Pharmacy Section Executive Committee established a working group to produce guidelines in this area in 1992. Having realized the importance of continuing to increase awareness of GPP and

stimulating its implementation, the FIP Bureau decided to request the BPP to focus on the theme and to develop a specific activity. They are the ones most frequently exposed to such products which may be inefficacious or toxic products, and which threaten to erode confidence in the health care system. It was for this reason that in May 1994 the Forty-seventh World Health Assembly, in adopting resolution WHA47.12 on the role of the pharmacist in support of the WHO revised drug strategy, drew attention to pharmacists' responsibilities in assuring the quality of the products they dispense.

The paper, entitled "GPP in Developing Countries – Guidelines for Implementation", was endorsed by the FIP CPS Executive Committee in September 1998.

These guidelines were developed as a reference to be used by national pharmaceutical organizations, governments, and international pharmaceutical organizations to set up nationally accepted standards of Good Pharmacy Practice.

The GPP Guidelines are based on the pharmaceutical care given by pharmacists. The guidelines recommend for national standards to be set:

- The promotion of health;
- The supply of medicines, medical devices, patient self-care;
- Improving prescribing and medicine use by pharmacists' activities.

These guidelines have been subsequently adapted and adopted in a wide number of developed countries. In certain cases, the national professional body has strived to adapt the guidelines and developed, in collaboration with the government, specific regulation/legislation on this matter.

1.4. New paradigm for pharmacy practice

The practice of pharmacy has changed significantly in recent decades. In the 1950s, pharmacists' responsibilities centered on dispensing and compounding drugs, and they rarely communicated with patients about their medications or disease processes.[1] With the introduction of "clinical pharmacy," however, the pharmacist's

attention began to shift from the medication itself to the interaction between the patient and the medication. Today, the pharmacist's role in many practice settings has expanded to include not only dispensing functions, but also direct contact with patients and other providers.

Medicines use has grown dramatically, the population has aged, the prevalence of chronic disease has increased, new infectious diseases have emerged and the range of effective medications has broadened, the new medical technology has opened, the number of medicines on the market has increased dramatically over the last few decades, bringing some real innovations but also considerable challenges in controlling the quality and rational use of medicines and change the role of the pharmacists.

In developing and industrialized countries alike, efforts to provide health care, including pharmaceutical care, are facing new challenges. These include the rising costs of health care (table 1.2), limited financial resources, a shortage of human resources in the health care sector, inefficient health systems, the huge burden of disease, and the changing social, technological, economic and political environment which most countries face. While globalization has brought countries closer together in trade of products and services and in recognition of academic degrees and diplomas, for example, it has led to rapid changes in the health care environment and to new complexities due to increased travel and migration.

National medicines policies have become an integral part of many countries' national health policies. At the international level, there are moves to harmonize approaches worldwide – an approach that warrants greater attention in view of the global reach of the pharmaceutical industry and pharmacy practice.

At community and population level, pharmaceutical practice comprises the activities which support the other levels (i.e., information, education and communication to promote public health, the provision of medicines information, research, dissemination of new information, education and training of staff, consumer groups, community-based organizations and health system researchers).

Table 1.2.

Total expenditure on health, % gross domestic product												
	1960	1970	1980	1990	2000	2005	2006	2007	2008	2009	2010	
Australia	3,6		6,1	6,7	8,0	8,4	8,5	8,5	8,7			
Austria	4,3	5,2	7,4	8,3	9,9	10,4	10,3	10,3	10,4	11,0		
Belgium		3,9	6,3	7,2	8,1	10,1	9,6	9,7	10,1	10,9		
Canada	5,4	6,9	7,0	8,9	8,8	9,8	10,0	10,0	10,3	11,4	11,3	
Denmark			8,9	8,3	8,7	9,8	9,9	10,0	10,3	11,5		
France	3,8	5,4	7,0	8,4	10,1	11,1	11,0	11,0	11,1	11,8		
Germany		6,0	8,4	8,3	10,3	10,7	10,6	10,5	10,7	11,6		
Iceland	3,0	4,7	6,3	7,8	9,5	9,4	9,1	9,1	9,1	9,7	9,3	
Italy				7,7	8,1	8,9	9,0	8,7	9,0	9,5	9,6	
Korea			3,7	4,0	4,5	5,7	6,0	6,3	6,5	6,9	7,0	
Mexico				4,4	5,1	5,9	5,7	5,8	5,8	6,4	6,1	
New Zealand		5,2	5,8	6,8	7,6	8,7	9,1	8,8	9,6	10,3		
Norway	2,9	4,4	7,0	7,6	8,4	9,1	8,6	8,9	8,6	9,6		
Spain	1,5	3,5	5,3	6,5	7,2	8,3	8,4	8,5	9,0	9,5		
Sweden		6,8	8,9	8,2	8,2	9,1	8,9	8,9	9,2	10,0		
Switzerland	4,9	5,5	7,4	8,2	10,2	11,2	10,8	10,6	10,7	11,4	11,6	
United Kingdom	3,9	4,5	5,6	5,9	7,0	8,2	8,5	8,4	8,8	9,8		
United States	5,1	7,1	9,0	12,4	13,7	15,7	15,8	16,0	16,4	17,4		

Source: OECD Health Data 2011
http://stats.oecd.org/Index.aspx?DataSetCode=SHA

Health promotion, disease prevention and lifestyle modification are activities at community level that have a public health focus. Pharmacists can offer public health interventions more conveniently than other groups since they are easily accessible and recognized as experts in matters of health. Pharmacists are a trusted source of information and advice on health and medicines. However, they cannot operate in isolation and must accept joint responsibility with all health professionals to serve community and public health goals.

Access to medicines of assured quality remains a major concern worldwide. One third of the world's populations do not yet have regular access to essential medicines. For many people, the affordability of medicines is a major constraint. Those hardest hit are patients in developing and transitional economies, where

50%–90% of medicines purchased are paid for out-of-pocket. The burden falls most heavily on the poor, who are not adequately protected either by current policies or by health insurance. The logistical aspects of distribution – often seen as the pharmacist's traditional role, especially in health institutions – represent another challenge. Moreover, in many developing countries 10%–20% of sampled medicines fail quality control tests.

A Statement on Ensuring the Quality and the Safety of Medicinal Products to Protect the Patient was jointly signed by FIP and the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) in 2000. Its common goal is to protect the well-being of patients in all parts of the world by ensuring that all medicinal products are of good quality and proven safety and efficacy. Both the pharmaceutical industry and the pharmaceutical profession also recognized the need for a regulatory and marketing environment which encourages investment in new innovative medicines and allows their timely introduction and availability to patients worldwide.

Another major challenge is ensuring that medicines are used rationally. This requires that patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements for an adequate period of time, and at the lowest cost to them and their community.

However, rational use of medicines remains the exception rather than the rule. For those people who do receive medicines, more than half of all prescriptions are incorrect and more than half of the people involved fail to take them correctly. In addition, there is growing concern at the increase in the global spread of antimicrobial resistance, a major public health problem. A recent report by WHO revealed findings of up to 90% resistance to original first-line antibiotics such as ampicillin and cotrimoxazole for shigellosis, up to 70% resistance to penicillin for pneumonia and bacterial meningitis, up to 98% resistance to penicillin for gonorrhoea, and up to 70% resistance to both penicillins and cephalosporins for hospital-acquired staphylococcus aureus infections.

In 2000, the FIP Council adopted a Statement of Policy on Control of Resistance to Antimicrobials which provides a list of recommendations for governments and health authorities on the appropriate measures needed to combat antimicrobial resistance. The statement also declares that pharmacists are ready to collaborate actively with physicians, regulatory authorities and other health professionals in efforts to combat antimicrobial resistance and to participate in public information campaigns on this.

These challenges – both to access to medicines of assured quality and to their rational use – underscore the urgency of the need for global health sector reform. Against this backdrop of ongoing and profound changes in health care delivery systems, a paradigm shift in pharmacy practice is occurring. Public health interventions, pharmaceutical care, rational medicine use and effective medicines supply management are key components of an accessible, sustainable, affordable and equitable health care system which ensures the efficacy, safety and quality of medicines. It is clear that pharmacy has an important role to play in the health sector reform process. To do so, however, the role of the pharmacist needs to be redefined and reoriented. Pharmacists have the potential to improve therapeutic outcomes and patients' quality of life within available resources, and must position themselves at the forefront of the health care system. The movement towards pharmaceutical care is a critical factor in this process. While efforts to communicate the correct information to patients are as important as providing the medicine itself, pharmacists also have a vital contribution to make to patient care through managing drug therapy and concurrent non-prescription or alternative therapies.

This changing vision for the practice of pharmacy got an important boost in 1990, when Hepler and Strand coined the term "pharmaceutical care." Over the next decade, it became a buzz word promoted by pharmacy organizations. Pharmaceutical care embodies a patient-centered, outcomes-oriented practice of pharmacy. This practice model promoted the pharmacist as a key member of the healthcare team, with responsibility for the outcomes of medication therapy.

The emergence of the pharmacist's patient-centered role was reinforced in 2000 when the American College of Clinical Pharmacy issued a white paper, "A vision of pharmacy's future roles, responsibilities, and manpower needs in the United States." Two other major pharmacy organizations, the American Pharmacists Association (APhA) and the American Society of Health-System Pharmacists (ASHP), also have launched initiatives designed to support an expanded role for the pharmacist and to increase recognition of the profession.

And yet, many pharmacists complain that this transformation is not happening quickly enough, or going far enough. On discussion boards and blogs, as well as in private conversations, pharmacists note practice realities that seem to contradict the change in practice promoted by pharmacy leaders. As in many other professions, achieving true change has been a challenge, and many barriers still remain to be overcome.

The ability of pharmacists to provide true "pharmaceutical care" hinges on the redesign of the traditional pharmacy environment and services, according to the APhA, one of the largest professional pharmacy organizations. The group has called for such "revolutionary changes" as private consulting areas in pharmacies and pharmacist house calls. In fact, the APhA describes its mission as "adding value" to the pharmacist license via expanded patient services. Pharmacists are encouraged to provide new and innovative services such as immunization clinics, emergency contraceptives, and collaborative practice provisions for optimal medication therapy management.

Similarly, ASHP has been working to improve pharmacy practice for hospital pharmacists, as outlined in its landmark initiative, "Health-system Pharmacy 2015." The program has 6 goals and 31 specific objectives to make medication use more effective, scientific, and safe. The overarching goal is to raise the profile of the pharmacist from a quiet but valuable member of the healthcare team to a more visible and vital component of patient care. The specific goals were designed to reflect a realistic assessment of what could be accomplished by 2015.

1.5. The future of the pharmacy practice

Pharmacist is well-informed and certified to prepare and dispensing drugs and to afford drug and associated information to the community. The demand for trained pharmacy professionals has dramatically increased in recent years due the rapid growth of the health care and pharmaceutical industries, especially for the growing elderly population. In the coming decades, pharmacists are expected to become more integral within the health care system. Rather than simply dispensing medication, pharmacists will be paid for their patient care skills.

This shift has already commenced in some countries; for instance, pharmacists in Australia receive remuneration from the Australian Government for conducting comprehensive Home Medicines Reviews. In Canada, pharmacists in certain provinces have limited prescribing rights (as in Alberta and British Columbia) or are remunerated by their provincial government for expanded services such as medications reviews (Medschecks in Ontario). In the United Kingdom, pharmacists who undertake additional training are obtaining prescribing rights. They are also being paid for by the government for medicine use reviews. In the United States, pharmaceutical care or clinical pharmacy has had an evolving influence on the practice of pharmacy. Moreover, the Doctor of Pharmacy (Pharm. D.) degree is now required before entering practice and some pharmacists now complete one or two years of residency or fellowship training following graduation.

Today the latest concept in medicine is towards individualization of drug therapy. Where judicious patient care is needed individualization of drug therapy becomes a need, and a pharmacist can play a vital role in this. A physician who is preoccupied with patient diagnosis and treatment may not spare time for patient counseling regarding pharmaco-economics, drug information, alternative therapy, moral supporting etc. A pharmacist can set up a separate consultation room and provide counseling to the patient. He can store the details of patient history, allergies and other details necessary for therapy so that the concept of individualization of drug therapy could be implemented. To be effective health care team members,

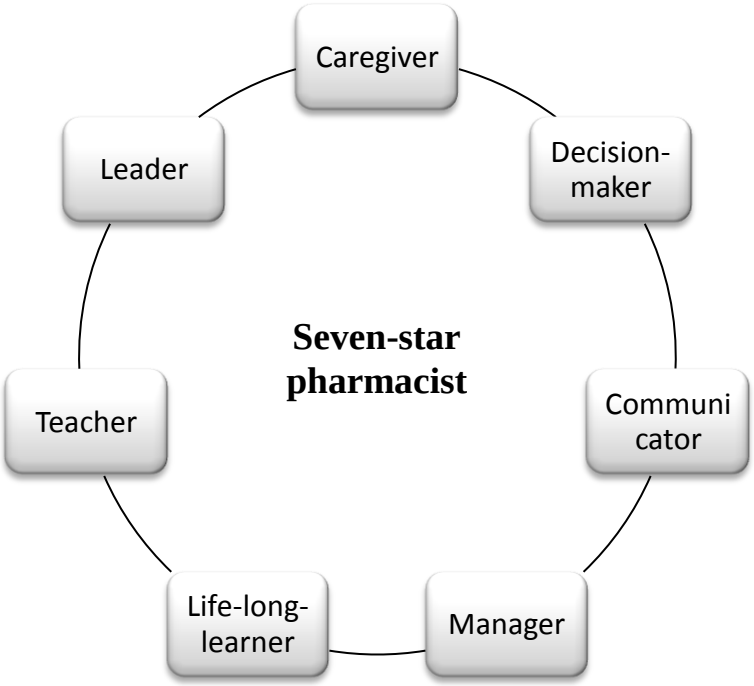
pharmacists need skills and attitudes enabling them to assume many different functions. Pharmacist of the future has been described as a seven star Pharmacist-some one who is equal in excellence to a five star hotel yet accessible to everyone from the richest to the poor. The concept of the "seven-star pharmacist" was introduced by WHO and taken up by FIP in 2000 in its policy statement on Good Pharmacy Education Practice to cover these roles: caregiver, decision-maker, communicator, manager, life-long learner, teacher and leader. A Pharmacist with the above skills and attitudes should make himself an indispensable partner in health care system of a nation.

Differences in approaches to pharmaceutical activity at different ages are shown in table 1.3.

Table 1.3.

Approaches to pharmaceutical activity in different centuries

Implicit in these roles is that of health promoter. The pharmacist's continuing relationship with the client, the community-based practice, and multiple entry points for counseling make the pharmacist a leader in health care.



Scheme 1.5. Functions of the seven-star pharmacist

The roles of the pharmacist (Scheme 1.5.) are described below and include the following functions:

- **Caregiver**: Pharmacists provide caring services. They must view their practice as integrated and continuous with those of the health care system and other health professionals. Services must be of the highest quality.

- **Decision-maker**: The appropriate, efficacious, safe and cost-effective use of resources (e.g., personnel, medicines, chemicals, equipment, procedures, practices) should be the foundation of the pharmacist's work. At the local and national levels, pharmacists play a role in setting medicines policy. Achieving this goal requires the ability to evaluate, synthesize data and information and decide upon the most appropriate course of action.

- **Communicator**: The pharmacist is in an ideal position to provide a link between prescriber and patient, and to communicate information on health and medicines to the public. He or she must be knowledgeable and confident while interacting with other health professionals and the public. Communication involves verbal, non-verbal, listening and writing skills.

- **Manager**: Pharmacists must be able to manage resources (human, physical and financial) and information effectively; they must also be comfortable being managed by others, whether by an employer or the manager/leader of a health care team. More and more, information and its related technology will provide challenges as pharmacists assume greater responsibility for sharing information about medicines and related products and ensuring their quality.

- **Life-long-learner**: It is impossible to acquire in pharmacy school all the knowledge and experience needed to pursue a life-long career as a pharmacist. The concepts, principles and commitment to life-long learning must begin while attending pharmacy school and must be supported throughout the pharmacist's career. Pharmacists should learn how to keep their knowledge and skills up to date.

- **Teacher**: The pharmacist has a responsibility to assist with the education and training of future generations of pharmacists and the public. Participating as a teacher not only imparts knowledge to others, it offers an opportunity for the practitioner to gain new knowledge and to fine-tune existing skills.

- **Leader**: In multidisciplinary (e.g., team) caring situations or in areas where other health care providers are in short supply or non-existent the pharmacist is obligated to assume a leadership position in the overall welfare of the patient and the community. Leadership involves compassion and empathy as well as vision and the ability to make decisions, communicate, and manage effectively. A pharmacist whose leadership role is to be recognized must have vision and the ability to lead.

And the added function of:

- **Researcher**: The pharmacist must be able to use the evidence base (e.g., scientific, pharmacy practice, health system) effectively in order to advise on the rational use of medicines in the health care team. By sharing and documenting experiences, the pharmacist can also contribute to the evidence base with the goal of optimizing patient care and outcomes. As a researcher, the pharmacist is able to increase the accessibility of unbiased health and medicines-related information to the public and other health care professionals.

These features also make the pharmacist a potential leader in prevention. None of this is new to the profession. Not many pharmacists may have reflected that, in prevention, the leadership role is two-fold, a formal function (leadership through giving high quality advice) and an informal one (leadership by example).

Thus, the current era of globalization has witnessed evolution in the professions of the health sector, especially in pharmacy. Over the past 50 years, the pharmacist's role has changed from that of compounder and dispenser to one of "drug therapy manager". Whereas previously the pharmacist worldwide was seen as responsible primarily for manufacturing and supplying medicines, today the pharmacist's role has evolved towards a clinical orientation. This involves responsibilities to ensure that wherever medicines are provided and used, quality products are selected, procured, stored, distributed, dispensed and administered so that they contribute to the health of patients, and not to their harm. The scope of pharmacy practice now includes patient-centred care with all the cognitive functions of counselling, providing drug information and monitoring drug therapy, as well as technical aspects of pharmaceutical services, including medicines supply management. It is in the additional role of managing drug therapy that pharmacists can now make a vital contribution to patient care.

The profession is still under continuous transition. With change in the health demands, pharmacists have a further role to play in patient care.

The precise role of a pharmacist in the health setting is altering and varies significantly from country to country. In contrast to the developed world, pharmacists in developing countries are not fully executing their potential role. They are still struggling for the recognition of their role that can help improve the health care system.

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Review questions

1. What is the mission of the pharmacy practice?
2. What kinds of professional services have to be provided by Pharmacists?
3. What basic international events and guidelines influence on pharmacy practice?
4. How has pharmacy changed in recent decades? Where pharmacists' responsibilities is centered now?
5. What means “seven-star pharmacist”? What are the functions of the seven-star pharmacist?

Check Your Understanding

1. Pharmacists are those who are educated and licensed to

A. dispense drugs and provide drug information.
B. dispense information but not drugs.
C. dispense alternative remedies rather than the drags prescribed.
D. test pharmacy technicians and provide their certification.

2. The key elements of professionals in the pharmacy include all of the following, except

A. using proper judgment.
B. having good typing skills.
C. having specific attitudes that influence professional behavior."
D. possessing relevant professional knowledge about drugs.

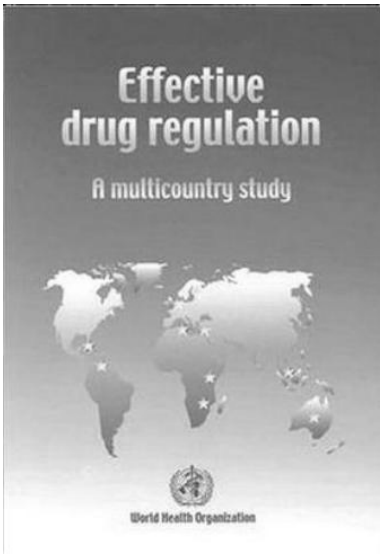
3. Pharmacy is

A. the art of drug therapy.
B. only about drug product selection.
C. exclusively about interpreting prescriptions from doctors' handwriting.
D. the art and science of dispensing and preparing medication and providing drag-related information to the public.

Chapter 2. STATE MANAGEMENT AND REGULATION OF PHARMACEUTICAL ACTIVITY

2.1. Regulation as function of state management

Government administration is an organizational and regulatory activities of the government, aimed at areas and sectors of society that need this intervention. Government Management of Pharmacy based on Government policy, coordination, control and supervision over the observance of all pharmaceutical organizations as entities and regulatory and local authorities, the existing legal regulations.



Government economic policy is a strategy of targeting economic processes at the macro and micro level, creating and improving conditions for economic development according to a certain social order.

Regulation can be defined as any measure or intervention implemented under government authority that acts to control the behaviour of individuals or groups that come within the ambit of that authority. Regulation includes the primary laws and subordinate instruments developed by government and the rules issued by government and non-government agencies under delegated powers.

Ukraine's policy in health care is defined as a set of accepted national decisions or commitments to preserve and strengthen the physical and mental health of the population of Ukraine as an essential part of its national wealth by implementing set of political, institutional, economic, legal, social, cultural scientific, medical and preventive measures to preserve the gene fund of the Ukrainian nation, its humanitarian potential and taking into account the requirements of present and future generations the benefit of a specific person (individual) and society as a whole.

The Organisation for Economic Cooperation and Development (OECD) identifies three categories of regulation:

- economic regulations which intervene directly in market decisions.

- social regulations which protect public interests such as health and safety, the environment and social cohesion; and
- administrative regulations which are administrative and paperwork requirements through which governments collect information and impact on individual decision making through the requirement for licensing et cetera.

The government administration in pharmacy based on policy-making, coordination, control and supervision over the observance of all pharmaceutical organizations as entities and regulatory and local authorities, current regulations.

State policy in health care is defined as the set of accepted national decisions or commitments to preserve and strengthen the physical and mental health of the population of the country as an essential component of national wealth through the implementation of population policy, institutional, economic, legal, social, cultural, research, prevention and health measures to preserve the gene pool of the nation, its humanitarian potential and taking into account the requirements of present and future generations in the interest of a specific person (individual) and society as a whole.

The main targets of the government regulation are shown at the scheme 2.1.

Scheme 2.1. The main targets of the government regulation

The main functions of government regulation are (scheme 2.2.):

♣ Target: defining objectives, priorities (Latin prior - first preference) and the main directions of development of the national economy;

♣ Stimulating: the formation of controllers that can effectively influence the activity of economic entities (their interests) and stimulate economic processes in the desired direction for society;

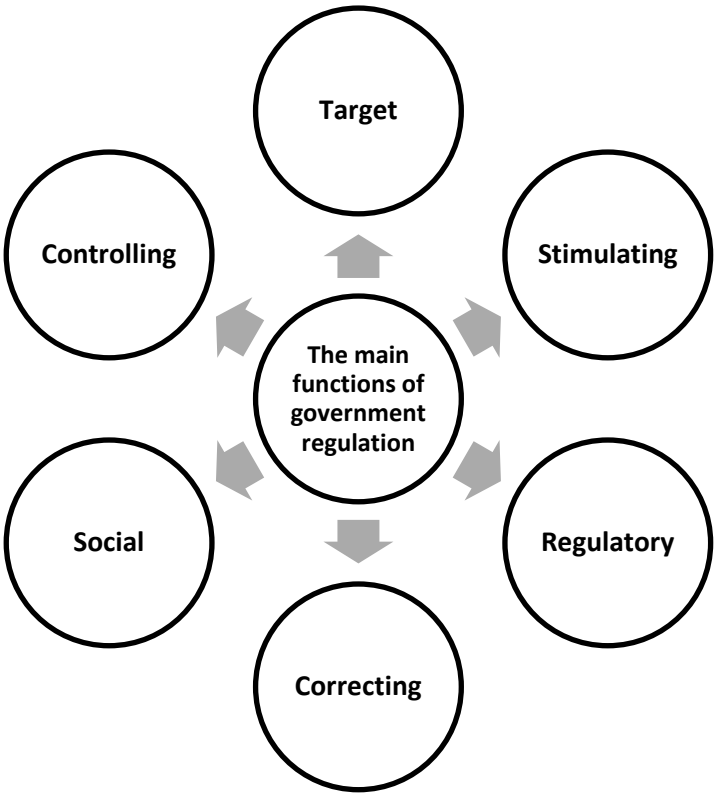
♣ Regulatory: establishment of certain rules of state for economic actors through laws and regulations;

♣ Correcting: adjusting the allocation of resources for the development of advanced processes and ensure normal social and economic conditions of society;

♣ Social: state regulation of social and economic relations, income redistribution, social protection and social guarantees, environmental conservation, etc.;

♣ Direct management of non-market sector of the economy: the regulation of the public sector, the creation of public goods and benefits;

♣ Controlling: State supervision and monitoring compliance with laws, regulations, economic, environmental and social standards and so on.



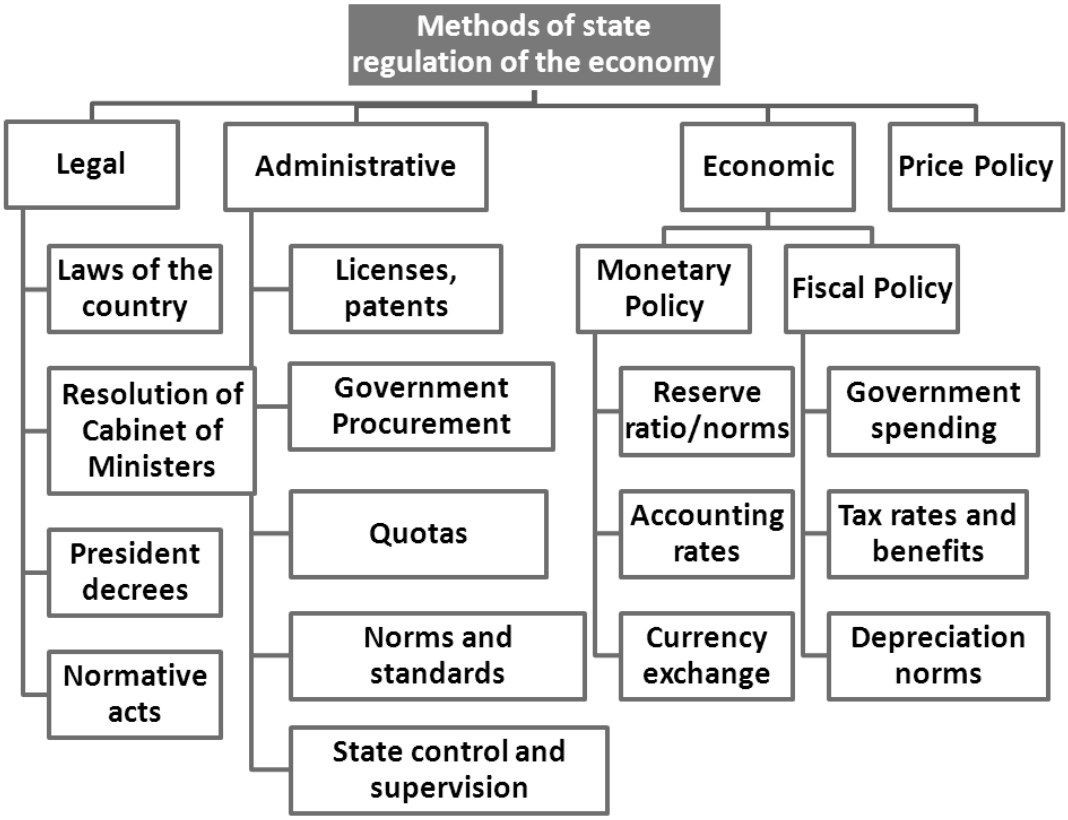
Scheme 2.2. The main functions of government regulation

Government regulation is a way to achieve social and economic goals through scientifically proven effect on the formation of development areas of economy. Goals and priorities for socio-economic development of are the basis of regulated entities. The objectives defined for the economic development of the country as a whole, its individual regions, institutional units, groups and be specific and quantified. Priorities are the most important socio-economic processes that are directed at stimulating certain period in the majority of resources with relevant regulators.

The object of the regulation is the economy of the country, regions, provinces, cities and counties, as well as socio-economic processes: the business cycle, economic structure, investment, and innovation processes, currency, inflation rates, balance of payments, block social problems and so on. The subject of regulation is the state represented by state authorities (President, Parliament, Government, local administrations) that to solve complex social and economic problems, comprehensive consideration of interests involving research institutions, political parties, social and religious organizations.

Methods of government regulation can be divided by their influence into direct and indirect, as well as the means of influence on the economic system - legal, administrative, organizational and economic (Scheme 2.3. and Table 2.1).

Methods of direct exposure directly influence on the functioning of the market using the tools of administrative law, which regulate the activities of the entity and specific economic instruments. The main instruments of direct government regulation are: defining objectives of economic development; State earmarking; providing targeted subsidies; installation and limit prices; quotas on production, import and export of products; licensing and real exports and imports; the state examination and state standards; establish regulatory requirements for quality and certification technologies and products, and others. Direct methods of state regulation of the economy are related to the creation of additional incentives and are based on the strength of the government.



Scheme 2.3. Methods of state regulation of the economics

Table 2.1

	Methods of state regulation of the economy	
	Direct methods	Indirect methods
Definition	Methods of direct effect are directly influenced by the functioning of the market using the tools of administrative law, which regulate the activities of business entities and certain economic instruments.	Methods of indirect regulation are influenced on the behavior of economic agents indirectly through the creation of economic environment that forces them to act in the right direction.
The main instruments of the method	regulations, macroeconomic plans targeted integrated programs, public order, licenses, quotas, state budget expenditures, limits, etc.	tools of fiscal, budgetary, monetary, investment, depreciation, innovation and other areas of economic policy, as well as methods of moral persuasion.

Methods of indirect regulation are the methods that affect the behavior of economic agents, indirectly, through the creation of a certain economic environment that forces them to act in the right direction state. The methods of indirect regulation instruments are fiscal, monetary, pricing, investment and other areas of economic policy. Among the assets may be distinguished: the establishment of a system of taxes, tax benefits; providing benefits in lending; manipulating interest rates, refinancing; regulating the exchange rate of the national currency; customs regulation of exports and imports; setting exchange rates and terms of exchange and so on.

2.2. Organizational structure and controls the pharmaceutical industry

The pharmaceutical industry is a complex socio-economic system, which includes:

♣ producers of pharmaceutical products;

♣ pharmaceutical base, wholesalers, subsidiaries of foreign pharmaceutical companies;

♣ pharmacies of different forms of ownership and management;

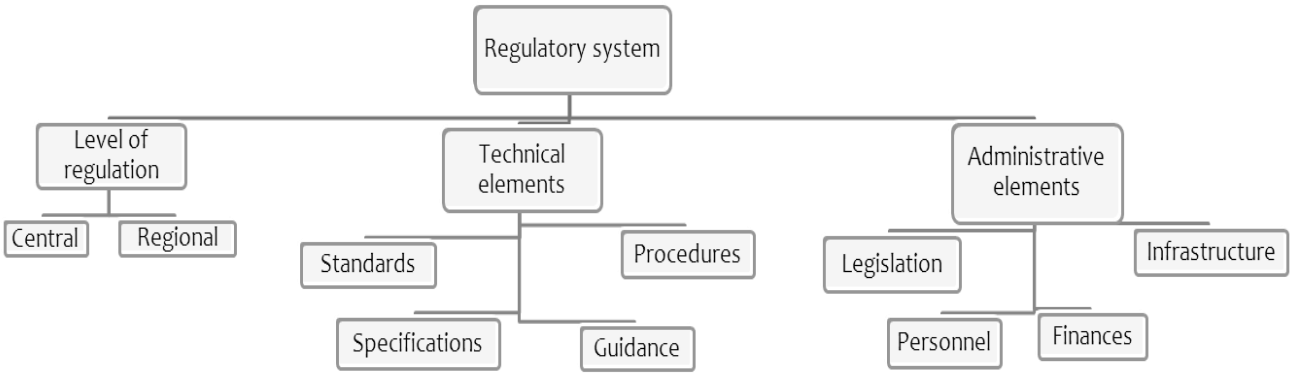
♣ territorial public drugs service;

♣ research institutions;

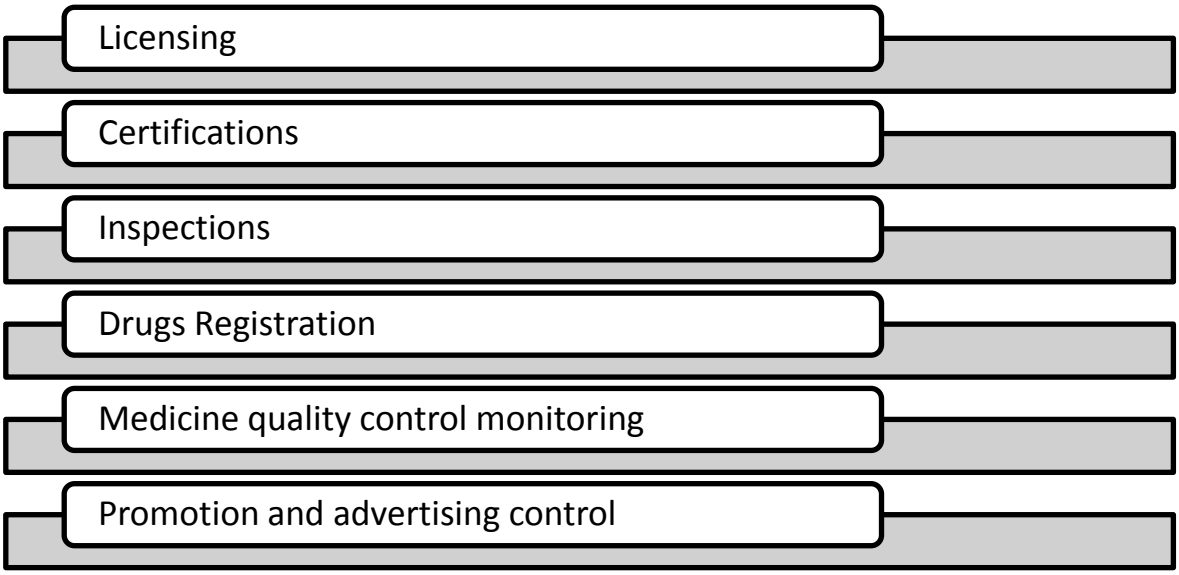
♣ higher pharmaceutical schools, university;

♣ Association of Pharmaceutical employees.

WHO recommendes regulated levels, technical and administrative elements, regulatory functions for the national regulatory system in pharmaceutical providing (scheme 2.4.-2.5).



Scheme 2.4. WHO recommendation for the national regulatory system



Scheme 2.5. Regulatory functions in pharmaceutical providing

What is regulation needs for? Expected results of the pharmaceutical regulation are shown at scheme 2.6.

Scheme 2.6. Expected results of the pharmaceutical regulation

A necessary condition for the effective functioning of this system is the ordered structure of government, which provided a clear division of functions and powers

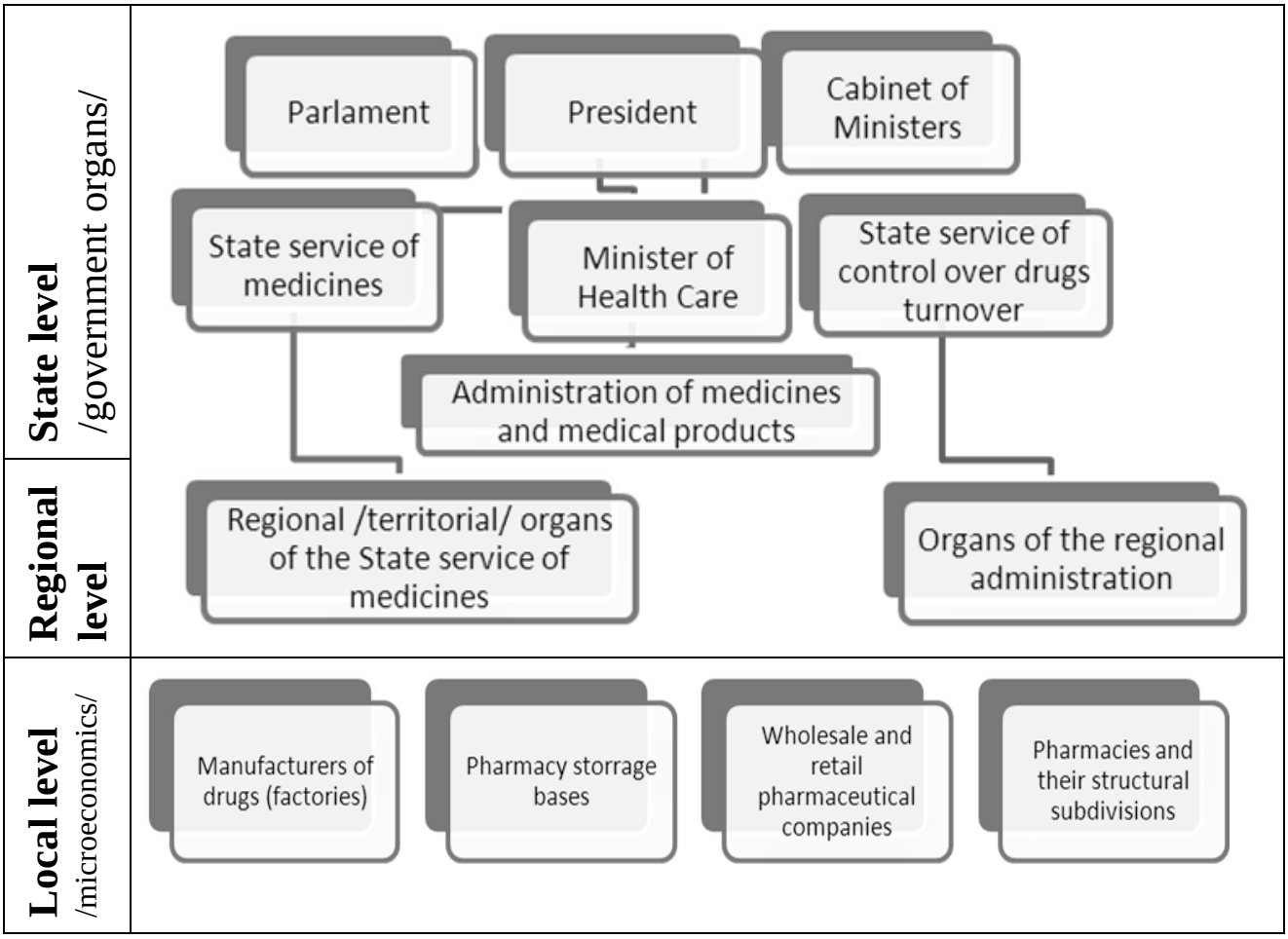
between levels of management. The modern scheme of the government management of the pharmaceutical industry shown at scheme 2.7.

Ministry of Health care in Ukraine is the main body in the system of central executive authorities to ensure the implementation of state policy in the field of health, sanitary and epidemiological welfare of population, development, manufacturing, quality control and sale of medicines and medical purpose.

The main tasks of the Ministry of Health care Ukraine are:

♣ formulation and implementation of national policy on health care;

♣ state policy in the field of sanitary and epidemiological welfare of population, development, manufacturing, quality control and sale of drugs, medical immunobiological drugs and medical devices, combat HIV / AIDS and other socially dangerous diseases.



Scheme 2.7. Government management of the pharmaceutical industry

State Service of Ukraine on Medicinal Products is a central executive body whose activities are directed adopts and coordinated by the Cabinet of Ministers through the Minister of Health of Ukraine. Its main tasks are:

♣ propose public policy in the areas of quality and safety of drugs, medical devices;

♣ implementation of state policy in the sphere of the quality and safety of drugs and medical devices;

♣ licensing of drug manufacturing, wholesale and retail sale of medicines.

Ukraine State Service on Drug Control is a central executive body whose activities are directed adopts and coordinated by the Cabinet of Ministers of Ukraine. It is the main body in the system of central bodies of executive power in the formulation and implementation of national policy on narcotic drugs, psychotropic substances, their analogues and precursors combating illicit trafficking, as well as coordination of authorities on these issues.

2.3. Licensing of the pharmaceutical activity

State regulation of the pharmaceutical activity is designed to control two different aspects of the pharmacy: practice of the occupation of the pharmacy and the traffic in drugs.

The laws designed to control the practice of pharmacy have taken the form of occupational licensing laws and have been administered by boards or commissions composed of licensed pharmacists, whereas laws controlling drug traffic have been administered by other agencies.

Every state has laws and regulations guiding pharmacy standards and requirements, addressing issues such as required licenses for each facility and for the credentialed pharmacists and other employees who work there. Virtually every jurisdiction also has requirements for secure storage, recordkeeping, the forms or pads used for patient prescriptions, labeling, and safety protocols related to origins, authenticity, chain of custody, expiration dates of products, purity, sterility and

storage, among others. This includes the extra, explicit authority granted to "compound" or mix pharmaceutical ingredients into a patient-ready product. Numerous existing pharmacies have the authority to prepare such products for patients, based on prescriptions written by doctors or other prescribers.

Regulating the practice of pharmacy includes examining applicants for licensure, issuing licenses to those who qualify, and setting and enforcing minimum standards governing the operatios of pharmacists and pharmacies.

Analysis of the principles of state regulation of drugs of the pharmaceutical legislation shows that the main component of regulatory policy is the licensing of pharmaceutical, pharmacy law, drug pricing and Reimbursement (table 2.2).

Table 2.2

State regulation of the pharmaceutical legislation of the EU

Methods of the state regulation of the pharmaceutical activity	Countries															
	Great Britain	Italy	Holland	France	Portugal	Norway	Denmark	Belgium	Germany	Finland	Austria	Sweden	Switzerland	Poland	Czech	Slovakia
Licensing and certification of drugs	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔
Registration (registers, lists)	✔		✔			✔		✔		✔	✔	✔		✔		✔
Monitoring of drugs after registration	✔					✔	✔									
Licensing of manufacturing, wholesale and retail sales		✔		✔		✔	✔		✔	✔				✔		
Pharmacy law: limiting the number of pharmacies, property, etc.	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔
Medicine pricing	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔
Reimbursement	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔

The basis of all the laws of the Member States concerning pharmacy is the Copenhagen Declaration, adopted May 31, 1994 at the European Forum pharmaceutical companies. Its main provisions are as follows:

- ✓ medication is not an ordinary commodity;
- ✓ pharmacist monitors the quality of drugs, guided in its activities crisp professional and ethical rules;
- ✓ pharmacist is the only specialist with appropriate qualifications required for decisions on assumption of drugs on the market. Education and continuous training allow pharmacists to exercise appropriate control over all phases of retail and trafficking of drugs to the health and safety of society.

A mandatory system of licensing manufacturers, importing agents and distributors is essential to ensure that all products conform to acceptable standards of quality, safety and efficacy. In addition, all premises and practices used to manufacture, store and distribute these products must comply with requirements to ensure continued conformity to standards until products are delivered to the end-user.

Before a formal licensing system can become operative, it is necessary to: adopt a precise definition of the various categories of licence-holders; determine the content and format of licences; detail the criteria on which licence applications will be assessed; and provide guidance to interested parties on the content and format of licence applications, and on the circumstances in which an application for renewal, extension or variation of a licence will be required.

Licensure is the process by which an agency of government grants permission to an individual to engage in a given occupation upon recognizing that the applicant has attained the minimum competency necessary to ensure that the public health, safety, and welfare will be reasonably well protected.

In most countries the law laid down certain restrictions on the licensing of pharmaceutical activities, namely:

- ✓ own or manage a pharmacy has a pharmacist;
- ✓ pharmacist may own only one pharmacy.

It has been said that pharmacists are the most regulated of all professions. The State Board of Pharmacy issues regulations which pharmacists must follow to assure the public health, safety and welfare.

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 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.

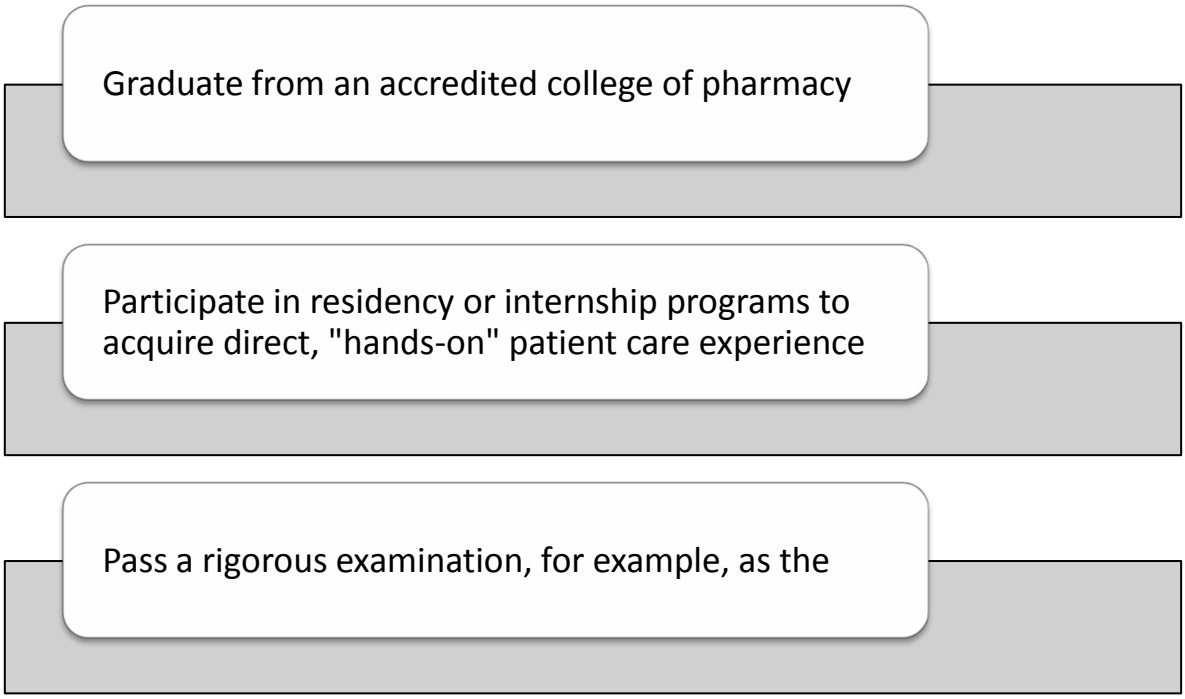
Basic principles of state policy in the fields of licensing are:

- providing of equality of right, legal interests of all subjects of managements;
- defense right, legal interests and health of citizens? external environment and providing of safety of the state;
- introduction of the same order of licensing of economic activity on the territory of all state;
- introduction of the same list economic activity which are subject to licensing.

To practice pharmacy in any state, a pharmacist must become a registered pharmacist (RPh), also known as a licensed pharmacist. Pharmacists are licensed by the State Organ of Pharmacy (Ministry of Health care). Requirements vary somewhat from state to state, but in general they are reflected at scheme 2.8.

The pharmacist's educational experience does not end upon being licensed. Most states require licensed pharmacists to take continuing education courses every year in order to maintain their licenses to practice. Pharmacists obtain this additional education through correspondence courses, attending professional meetings and seminars presented by pharmacy associations, or participating in courses provided by the schools and colleges of pharmacy.

Requirements vary somewhat from state to state, but in general, to be licensed a pharmacist must:



Scheme 2.8. Requirements to a licensed pharmacist

2.4. Licensing of the Pharmaceutical Activities in the intertnational practice

2.4.1. Licensing of the Pharmaceutical Activities in Ukraine

The organ of licensing is the organ of executive power defined by Cabinet of Ministers of Ukraine for licensing of certain types of economic 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 sales of definite type of economic activity, subject to licensing.

To get a licence 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.

2.4.2. Licensing of the Pharmaceutical Activities in Canada

Becoming a Pharmacist in Canada

In order to become a licensed pharmacist in Canada, you need:

- A bachelor's or doctor of pharmacy degree from one of ten Canadian universities
- To complete a national board examination through the Pharmacy Examining Board of Canada (PEBC) (with the exception of Québec)
- Practical experience through an apprenticeship/internship program
- Fluency in English or French

The profession of pharmacy is regulated on a provincial and territorial level. The regulatory authorities are directly responsible for granting pharmacist licenses, assessing the competency of pharmacists and ensuring public safety. For a detailed

look at the specific provincial licensing requirements in every province, visit the National Association of Pharmacy Regulatory Authorities (NAPRA).

Registration Requirements

Pharmacist

To practise as a pharmacist in Ontario, internationally educated pharmacists (IEPs) must hold a current Certificate of Registration with the OCP. To be eligible for a Certificate of Registration, IEPs must meet the following registration requirements:

1. Document evaluation by the Pharmacy Examining Board of Canada (PEBC).
2. Pass the PEBC Evaluating Examination for pharmacists.
3. *Completion of the International Pharmacy Graduate Program (see College's website).
4. Meet the OCP English or French fluency requirements.
5. Provide proof of Canadian citizenship, Permanent Residency or authorization to work in Canada.
6. Sign a declaration that includes confirmation that you have not been found guilty of or are the subject of a current proceeding of any pharmacy practice or drug-related offence or any criminal offence, or the subject of a health profession-related finding of professional misconduct, incompetence or incapacity.
7. Successfully complete structured practical training comprised of:
    1. a minimum of 12 weeks of Structured Practical Training (SPT) at the student level and,
    2. a minimum of 12 weeks of Structured Practical Training (SPT) at the intern level
8. Pass the PEBC Qualifying Examination for Pharmacists, Part I – MCQ and Part II - OSCE.
9. Pass the OCP Jurisprudence Examination for Pharmacists.
10. Provide proof of sufficient personal professional liability insurance.
11. Make an application and pay the fee.

2.4.3. Procedure for Licensure in California

To become licensed to practice pharmacy in California, you must meet the Registered Pharmacist requirements of the California Board of Pharmacy provided in the section on their website entitled Pharmacist Licensure Examinations.

The licensing process is primarily composed of two examinations and payment of fees (subject to change):

1) North American Pharmacist Licensure Exam (NAPLEX)

2) California Pharmacist Jurisprudence Examination (CPJE)

3) The following fees must be paid:

a) NAPLEX Application Fee: $505

b) California Pharmacist Licensure Application Fee: $200

c) Live Scan Processing Fee: DOJ Fee $32, FBI Fee $19 plus fingerprint scanning service fee that varies by location ($5- $20).

d) Self –Query Report Fee to NPDB - HIPDB: $16

e) California Pharmacist Jurisprudence Examination Fee: $33

f) California Pharmacist Licensure Fee: $150

Your applications for the NAPLEX and the CPJE are submitted separately

2.4.4. Licensing of the Pharmaceutical Activities in Austria

Community or Hospital Pharmacist

To be community or hospital pharmacist, you are obliged to do one year of practice (called “aspirancy year”) in a community or hospital pharmacy after getting your degree at the university. During this year, you learn the practical work in the pharmacies, and have to go to an additional course of 10 – 12 days held by the Austrian Chamber of Pharmacy. There you are taught the legal framework of our work and other matters, which are not taught at the university.

At the end of that year, you have to pass an exam at the Chamber under supervision of the Ministry of Health – if you succeed, you get the approbation to be

called “Apotheker” (Pharmacist) and may work in a pharmacy without supervision (no difference between community and hospital pharmacist).

For the first five years (full-time, 40h /week) after the exam, pharmacists may lead a pharmacy only temporarily for 6 weeks, when the head of the pharmacy is ill or on holiday.

After these five years, they may apply for the licence (called “Konzession”) of a community pharmacy, either to take over one already existing or to open a new one. In the first case, the pharmacist holding the licence has to hand it over to the new head.

By law, to get the licence for a new pharmacy, the pharmacist has to make sure, that the surrounding pharmacies are at a distance of at least 500m from the new one and that these pharmacies will still have more than 5.500 persons as potential patients. Every pharmacist may only have one licence; every pharmacy has to be led by a pharmacist with a licence. The licensed pharmacist can have partners, but he has to obtain 25% of the shares at the beginning and more than 50% after 10 years.

2.4.5. Licensing of the Pharmaceutical Activities in France

Pharmaceutical practice is regulated by the Code de la Santé publique both from an internal point of view (conditions of practice in the dispensary) and from an external point of view (external visibility of the dispensary).

The licensee is required to be assisted by one or more employed pharmacists when their turnover exceeds a certain level specified by ministerial order.

Pharmacy technicians (Article L.4241-1 of the Code de la santé publique) are solely authorised to assist the pharmacy owner and the employed pharmacists in the preparation and dispensing to the public of drugs intended for human and veterinary medicine. They assume their tasks under the responsibility of the actual control of a pharmacist. Their penal responsibility continues to be engaged.

By derogation from Article L.4241-1, pharmacy students duly enrolled on the third year of their studies in a pharmaceutical science training and research unit are authorised, for learning purposes, to carry out, outside university hours, the

operations referred to in his Article subject their having previously completed the dispensing course provided by the current legal provisions (Article L.4241-10 of the Code de la santé publique).

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Review questions

1. What is regulation?

2. What are the main goals and functions of the government regulation in pharmacy?

3. How can you classify the methods of the government regulation?

4. What kinds of State regulation of the pharmaceutical legislation in the EU you know?

5. What kind of activities are under licensing?

6. Indicate the basic licensed terms of pharmaceutical activity. What do you need to get licence to pharmaceutical activities?

Check Your Understanding

1. Pharmaceutical activity has features of government control, which are determined by its economic-market and social constituents. Define what does not belong to the economic mechanism of government control:

A Crediting

B Pricing

C Taxation

D Insurance

E Licensing

2. Sale of medicines and health care products for personal noncommercial use by the population throw the bank account or cashless independently of volumes of purchase must be carried out in accordance with license to right:

A Retail sales (sales) of medicines

B Wholesale sales (sales) of medicines

C Production of medicines

D Production of medicines in the pharmacy

E Retail and wholesale sales (sales) of medicines

3. Two pharmaceutical enterprises simultaneously applied to a bank for establishing a running account. The bank refused the application to one of the enterprises. The reason for the refusal is that the enterprise:

A Has no stamp

B Is located in another administrative area

C Has not registrated a statute

D Has not provided the balance

E Has not provided the report on financial results

4. A pharmacy got a license for the retail sales of medicines. Indicate the operation, which is NOT allowed by the license:

A Sales of the ready-made drugs to the ambulatory patients

B Sales of the ready-made drugs to the stationary patients

C Sales of commodities to establishments with future commercial use

D Free of charge sales to the chronic patients

E Sales of extemporeus drugs

5. Pharmaceutical activity has features of government control, which are determined by its economic-market and social constituents. Define what does not belong to the economic mechanism of government control:

A Crediting

B Pricing

C Taxation

D Insurance

E Licensing

Chapter 3. A NATIONAL DRUG POLICY AS A COMMON FRAMEWORK TO SOLVE PROBLEMS IN PHARMACEUTICALS

3.1. Problems of pharmaceutical providing

Health is a fundamental human right. Access to health care, which includes access to essential drugs, is a prerequisite for realizing that right. Essential drugs play a crucial role in many aspects of health care. If available, affordable, of good quality and properly used, drugs can offer a simple, cost-effective answer to many health problems. In many countries drug costs account for a large share of the total health budget. Despite the obvious medical and economic importance of drugs there are still widespread problems with lack of access, poor quality, irrational use and waste. In many settings essential drugs are not used to their full potential.

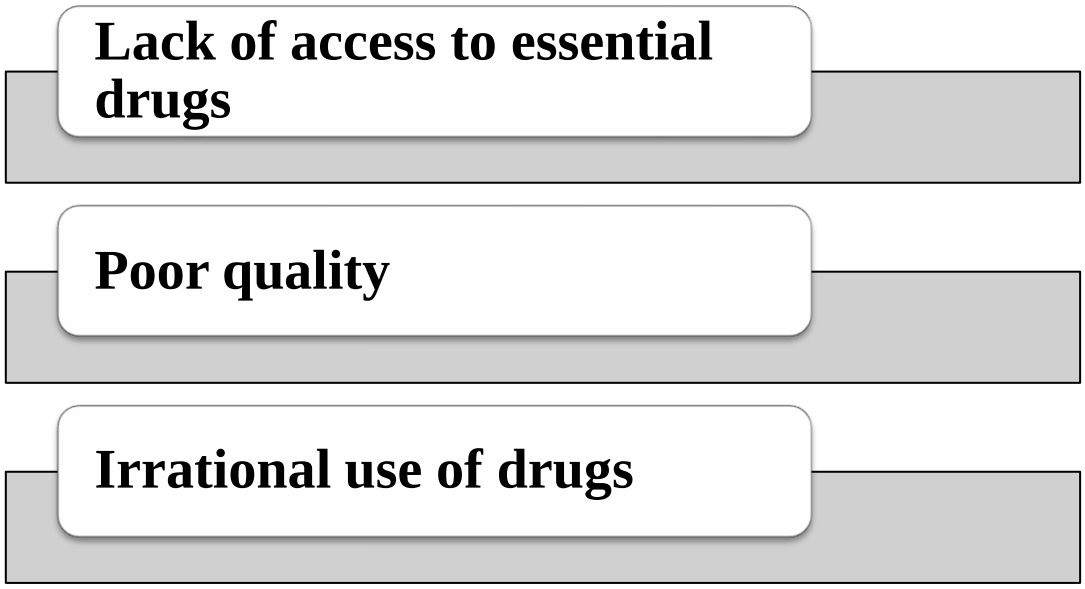

Fig 3.1. Problems of pharmaceutical providing

Lack of access to essential drugs

An increasing number of pharmaceutical products are available in the world market, and there has been rapid growth in both drug consumption and expenditure. However, many people throughout the world cannot obtain the drugs they need, either because they are not available or too expensive, or because there are no adequate

facilities or trained professionals to prescribe them. Although hard data are unavailable, WHO has estimated that at least one-third of the world's population lacks access to essential drugs; in poorer areas of Asia and Africa this figure may be as high as one-half. 2 Millions of children and adults die each year from diseases that could have been prevented or treated with cost-effective and inexpensive essential drugs.

Poor quality

In many countries drug quality assurance systems are inadequate because they lack the necessary components. These components include adequate drug legislation and regulations, and a functioning drug regulatory authority with adequate resources and infrastructure to enforce the legislation and regulations. Without these, substandard and counterfeit products can circulate freely. In addition, inappropriate handling, storage and distribution can alter the quality of drugs. All these factors may have serious health consequences and lead to a waste of resources.

Irrational use of drugs

Even people who have access to drugs may not receive the right medicine in the right dosage when they need it. Many people buy, or are prescribed and dispensed, drugs that are not appropriate for their needs. Some use several drugs when one would do. Others use drugs that carry unnecessary risks. The irrational use of drugs may unnecessarily prolong or even cause ill-health and suffering, and results in a waste of limited resources.

Persistent problems and new challenges

These problems have persisted despite all the work done to improve access to essential drugs, to ensure drug quality and to promote rational drug use. The reasons are complex and go beyond simple financial constraints. To understand them it is necessary to look at the characteristics of the drug market, and to study the attitudes and behaviour of governments, prescribers, dispensers, consumers and the drug industry. Health sector development, economic reform, structural adjustment policies, trends towards liberalization, and new global trade agreements all have a potential impact on the pharmaceutical situation in many countries. They may also affect the ultimate goal of achieving equity in health.

Changes in the patterns of disease and drug demand also represent major challenges. The rise of new diseases, such as acquired immunodeficiency syndrome (AIDS), the re-emergence of other diseases and increasing drug resistance of potentially fatal diseases, such as malaria and tuberculosis, all contribute to increased spending on drugs and growing pressure on health resources. Changes in life expectancy and in lifestyles have led to an increase in chronic diseases and diseases of the elderly, and an increase in the need for drugs to treat these chronic diseases.

Even highly developed countries the health care system meets the same problems:

- Since 2008, US spent more than 17% of GDP on health care
- IOM reports: 98,000 deaths due to medical errors
- Rising healthcare costs: 1/3 of healthcare dollars spent on waste and annual cost of poor quality per covered employee is $2,000
- Rand report: only 55% of recommended care delivered

Experience in many countries has shown that these complicated and interdependent problems can best be addressed within a common framework, as piecemeal approaches can leave important problems unsolved and often fail. In addition, the different policy objectives are sometimes contradictory, and so are the interests of some of the stakeholders. On the basis of this experience, WHO recommends that all countries formulate and implement a comprehensive national drug policy (NDP).

3.2. A national drug policy as a common framework to solve problems in pharmaceuticals

A national drug policy is a commitment to a goal and a guide for action. It expresses and prioritizes the medium- to long-term goals set by the government for the pharmaceutical sector, and identifies the main strategies for attaining them. It provides a framework within which the activities of the pharmaceutical sector can be coordinated. It covers both the public and the private sectors, and involves all the

main actors in the pharmaceutical field. A national drug policy is needed for many reasons. The most important are:

■ to present a formal record of values, aspirations, aims, decisions and medium- to long-term government commitments;

■ to define the national goals and objectives for the pharmaceutical sector, and set priorities;

■ to identify the strategies needed to meet those objectives, and identify the various actors responsible for implementing the main components of the policy;

■ to create a forum for national discussions on these issues.

The consultations and national discussions preceding the drug policy document are very important, as they create a mechanism to bring all parties together and achieve a sense of collective ownership of the final policy. This is crucial in view of the national effort that will later be necessary to implement the policy. The policy process is just as important as the policy document.

The main objectives of ensuring equitable access, good quality and rational use are usually found in all national drug policies, but clearly not all of these policies are the same. The final definition of objectives and strategies depends on the level of economic development and resources, on cultural and historical factors, and on political values and choices. The guidelines set out here are intended to help countries develop and implement a comprehensive policy framework that is appropriate to their own needs, priorities and resources.

A national drug policy is an essential part of health policy

A national drug policy cannot be developed in a vacuum – it must fit within the framework of a particular health care system, a national health policy and, perhaps, a programme of health sector reform. The goals of the national drug policy should always be consistent with broader health objectives, and policy implementation should help to achieve those broader objectives.

The health policy and the level of service provision in a particular country are important determinants of drug policy and define the range of choices and options.

On the other hand, the drug situation also affects the way in which health services are regarded. Services lose their credibility if there is no adequate supply of good quality drugs, or if these are badly prescribed. Thus the implementation of an effective drug policy promotes confidence in and use of health services.

There are also economic arguments. In many countries a large proportion of health care spending is on drugs. Health care financing is therefore closely related to drug financing. It is very difficult to implement a health policy without a drug policy.

Objectives of a national drug policy

In the broadest sense a national drug policy should promote equity and sustainability of the pharmaceutical sector.

The general objectives of a national drug policy are to ensure (fig.3.2.):

■ Access: equitable availability and affordability of essential drugs

■ Quality: the quality, safety and efficacy of all medicines

■ Rational use: the promotion of therapeutically sound and cost-effective use of drugs by health professionals and consumers.

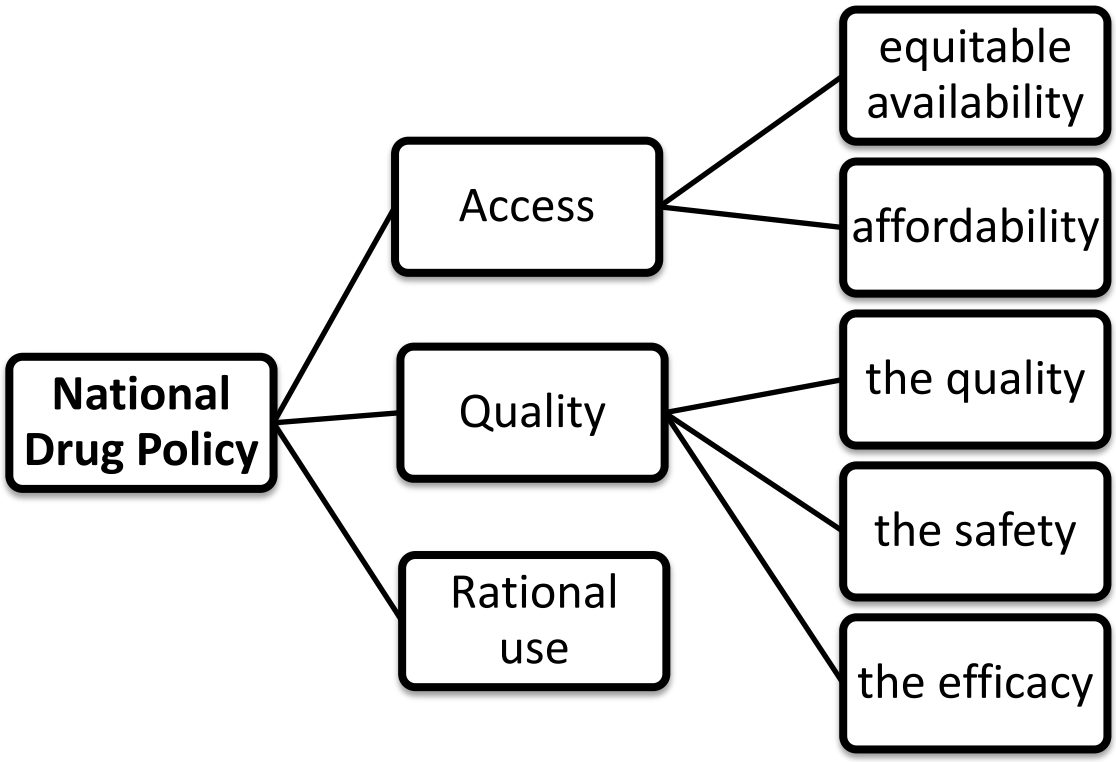

Fig. 3.2. Objectives of a national drug policy

The more specific goals and objectives of a national policy will depend upon the country situation, the national health policy, and political priorities set by the government. In addition to health-related goals there may be others, such as economic goals. For example, an additional objective may be to increase national pharmaceutical production capacity.

It is critical that all the drug policy's objectives are explicit, so that the roles of the public and private sectors and of the various ministries (health, finance, trade and industry) and government bodies (such as the drug regulatory authority) can be specified.

Importance of the essential drugs concept

The essential drugs concept is central to a national drug policy because it promotes equity and helps to set priorities for the health care system. The core of the concept is that use of a limited number of carefully selected drugs based on agreed clinical guidelines leads to a better supply of drugs, to more rational prescribing and to lower costs.

The reasons are clear. Essential drugs, which are selected on the basis of safe and cost-effective clinical guidelines, give better quality of care and better value for money.

The procurement of fewer items in larger quantities results in more price competition and economies of scale. Quality assurance, procurement, storage, distribution and dispensing are all easier with a reduced number of drugs. Training of health workers and drug information in general can be more focused, and prescribers gain more experience with fewer drugs and are more likely to recognize drug interactions and adverse reactions.

By the end of 1999, 156 developed and developing countries had national or institutional lists of essential drugs for different levels of care, in both the private and public sectors; 127 of these lists had been updated in the previous five years, and 94 were divided into levels of care. There is substantial evidence that the use of national lists of essential drugs has contributed to an improvement in the quality of care and to a considerable saving in drug costs.

3.3. Key components of a national drug policy

A national drug policy is a comprehensive framework in which each component plays an important role in achieving one or more of the general objectives of the policy (access, quality and rational use). The policy should balance the various goals and objectives, creating a complete and consistent entity. For example, access to essential drugs can only be achieved through rational selection, affordable prices, sustainable financing and reliable health and supply systems. Each of the four components of the "access framework" is essential but not sufficient in itself to ensure access. Similarly, rational drug use depends on many factors, such as rational selection, regulatory measures, educational strategies and financial incentives.

Table 3.1 lists the key components of a national drug policy and shows how they relate to the three main objectives of the policy.

Table 3.1

Components of a national drug policy, linked to key policy objectives

	Objectives	**Access**	**Quality**	**Rational use**
Components	Selection of essential drugs	X	(X)	X
	Affordability	X		
	Drug financing	X		
	Supply systems	X		(X)
	Regulation and quality assurance		X	X
	Rational use			X
	Research	X	X	X
	Human resources	X	X	X
	Monitoring and evaluation	X	X	X

X = direct link; (X) = indirect link

As can be seen from the Table, most components cannot be linked to one objective only.

Selection of essential drugs

Drug selection, preferably linked to national clinical guidelines, is a crucial step in ensuring access to essential drugs and in promoting rational drug use, because no public sector or health insurance system can afford to supply or reimburse all drugs that are available on the market. Key policy issues are:

■ the adoption of the essential drugs concept to identify priorities for government involvement in the pharmaceutical sector, and especially for drug supply in the public sector and for reimbursement schemes;

■ procedures to define and update the national list(s) of essential drugs;

■ selection mechanisms for traditional and herbal medicines.

How to develop and implement a national drug policy

Affordability

Affordable prices are an important prerequisite for ensuring access to essential drugs in the public and private sectors. Key policy issues are:

■ government commitment to ensuring access through increased affordability;

■ for all drugs: reduction of drug taxes, tariffs and distribution margins; pricing policy;

■ for multi-source products: promotion of competition through generic policies, generic substitution and good procurement practices;

■ for single-source products: price negotiations, competition through price information and therapeutic substitution, and TRIPS-compliant measures such as compulsory licensing, “early workings” of patented drugs for generic manufacturers and parallel imports.

Drug financing

Drug financing is another essential component of policies to improve access to essential drugs. Key policy issues are:

■ commitment to measures to improve efficiency and reduce waste;

■ increased government funding for priority diseases, and the poor and disadvantaged;

■ promotion of drug reimbursement as part of public and private health insurance schemes;

■ use and scope of user charges as a (temporary) drug financing option;

■ use of and limits of development loans for drug financing;

■ guidelines for drug donations.

Supply systems

The fourth essential component of strategies to increase access to essential drugs is a reliable supply system. Key policy issues are:

■ public–private mix in drug supply and distribution systems;

■ commitment to good pharmaceutical procurement practices in the public sector;

■ publication of price information on raw materials and finished products;

■ drug supply systems in acute emergencies;

■ inventory control, and prevention of theft and waste;

■ disposal of unwanted or expired drugs.

Regulation and quality assurance

The drug regulatory authority is the agency that develops and implements most of the legislation and regulations on pharmaceuticals, to ensure the quality, safety and efficacy of drugs, and the accuracy of product information. Key policy issues are:

■ government commitment to drug regulation, including the need to ensure a sound legal basis and adequate human and financial resources;

■ independence and transparency of the drug regulatory agency; relations between the drug regulatory agency and the ministry of health (MoH);

■ stepwise approach to drug evaluation and registration; definition of current and medium-term registration procedures;

■ commitment to good manufacturing practices (GMP), inspection and law enforcement;

■ access to drug control facilities;

■ commitment to regulation of drug promotion;

■ regulation of traditional and herbal medicines;

■ need and potential for systems of adverse drug reaction monitoring;

■ international exchange of information.

Rational use

The rational use of drugs means that patients receive medicines appropriate for their clinical needs, in doses that meet their individual requirements, for an adequate period of time, and at the lowest cost to them and their community. Irrational drug use by prescribers and consumers is a very complex problem, which calls for the implementation of many different interventions at the same time. Efforts to promote rational drug use should also cover the use of traditional and herbal medicines. Key policy issues are:

■ development of evidence-based clinical guidelines, as the basis for training, prescribing, drug utilization review, drug supply and drug reimbursement;

■ establishment and support of drugs and therapeutics committees;

■ promotion of the concepts of essential drugs, rational drug use and generic prescribing in basic and in-service training of health professionals;

■ the need and potential for training informal drug sellers;

■ continuing education of health care providers and independent, unbiased drug information;

■ consumer education, and ways to deliver it;

■ financial incentives to promote rational drug use;

■ regulatory and managerial strategies to promote rational drug use.

Research

Operational research facilitates the implementation, monitoring and evaluation of different aspects of drug policy. It is an essential tool in assessing the drug policy's impact on national health service systems and delivery, in studying the economics of drug supply, in identifying problems related to prescribing and dispensing, and in understanding the sociocultural aspects of drug use. Key policy issues are:

■ the need for operational research in drug access, quality and rational use;

■ the need and potential for involvement in clinical drug research and development.

3.4. Legislation and regulations of NDP

A legislative framework is needed in order to implement and enforce the various components of a national drug policy, and to regulate the activities of the different parties in both the public and private sectors.

Permitting the circulation of poor-quality, ineffective products and harmful ingredients in a country has an impact on the population's health and on the national economy. Lack of legislation and regulations on other aspects of pharmaceuticals, such as financing, supply and the use of drugs, affects cost-effectiveness in health delivery. Two types of legal framework cover pharmaceuticals. Laws are passed by a country's legislative bodies, and are formulated in general terms to meet current and future needs. Regulations enable government authorities to set out in more detail how the laws should be interpreted, and how they will be implemented and enforced. Regulations can be changed more easily than laws, and create the necessary flexibility in a changing environment. In some countries, regulations require only the approval of the head of a ministry or department.

Legislation and regulations ensure that the responsibilities, qualifications, rights and roles of each party are defined and recognized (including those of medical practitioners, pharmacists and the drug regulatory authority). They also create the legal basis enabling the regulatory control of activities such as drug manufacture, import, export, marketing, prescribing, dispensing and distribution, and the enforcement of such laws and regulations.

The purpose of the legislation is therefore the same as that of the drug policy: to ensure that only safe, effective, quality drugs are produced, imported and distributed, and that these drugs are made available, as well as managed and used appropriately.

Framework for drug legislation

Pharmaceutical legislation is mostly concerned with ensuring that effective and safe drugs of good quality are made available, and that correct information is provided about them. These tasks are covered in drug laws, pharmacy acts and drug regulations.

The drug regulatory authority is the enforcing body. There are also other laws and regulations that may support the implementation of the national drug policy, such as those that support generic substitution, those relating to patents and intellectual property rights, and tax laws. In some countries there are laws and regulations that deal with prescribing and dispensing practices to ensure the appropriate use of drugs. The most important aspects of a national drug policy which need legislative and regulatory support are listed in table 3.2.

Table 3.2

The components of a national drug policy which need political and legislative support

Component	**Political and legislative support on**
Selection of essential drugs	• Use of the national list of essential drugs • Selection and use of traditional medicines
Affordability	• Removal of import taxes on essential drugs • Distribution margins • Pricing policy • Generic policy, generic substitution • Equity pricing • Parallel import • Compulsory licensing
Drug financing	Increased government funding of drugs for priority diseases, the poor and disadvantaged • User charges, cost-sharing mechanisms • Support for health insurance and social security • Drug donations
Supply systems	• Public drug supply based on essential drugs list • Public-private mix in drug supply and distribution • Support to national pharmaceutical industry • Disposal of unwanted or expired drugs
Regulation and quality assurance	• Establishment and funding of the drug regulatory agency • Good manufacturing practices and other quality standards • Licensing of products, premises and personnel • Inspection • Quality control • Regulation of traditional and herbal medicines

Rational use	• Scheduling of drugs (over-the-counter, prescription-only) • Minimum requirements of professional training • Essential drugs concept as basis for training curricula • Training of informal drug sellers • Use of financial incentives for prescribers • Dissociation of prescribing/dispensing functions • Drug promotion
Research	• Clinical trials

Legislative models and structures for drug regulation vary from country to country, but the basic elements listed below represent a reasonable common framework.

The applicable legislation must be broad in its scope in order to address all the essential issues and be flexible enough to make the legislation specific to problems.

The list below in Table 3.3 can be useful as the basis for planning new drug laws or for revising existing legislation.

Table 3.3

Elements of drug legislation

What should be regulated	• Premises, persons and practices involved in the manufacture, importation, distribution, procurement, supply and sale of drugs, as well as the promotion and advertising of drugs. • Drug products.
Who regulates	• Governments have primary responsibility, but public and private professional associations also have a role to play.
Scope/extent of regulation	• Geographical area.
Which sanctions	• Administrative measures. • Legal sanctions (warnings, fines, withdrawal of licences, imprisonment).

Thus, the national drug policy is a commitment to a goal and a guide for action. It expresses and prioritizes the medium- to long-term goals set by the government for the pharmaceutical sector, and identifies the main strategies for attaining them. It provides a framework within which the activities of the pharmaceutical sector can be coordinated. It covers both the public and the private sectors, and involves all the main actors in the pharmaceutical field.

The national drug policy, presented and printed as an official government statement, is important because it acts as a formal record of aspirations, aims, decisions and commitments. Without such a formal policy document there may be no general overview of what is needed; as a result, some government measures may conflict with others, because the various goals and responsibilities are not clearly defined and understood.

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Review questions

1. What problems of the pharmaceutical providing do you know?
2. What are the basic principles of forming of the National pharmaceutical policy?
3. What are the reasons of the NDP implementation?
4. Call the objectives and key components of the NDP? Characterize their interrelations?
5. What components of the national drug policy need political and legislative support?

Check Your Understanding

1. Global targets of National medicinal politics include:

A Availability, quality, rational application

B Participating in process of drug use decision, lack of access to essential drugs

C Selecting the drug product dosage form, Irrational use of drugs

D Poor quality, Monitoring patient compliance

E Detecting adverse drug reaction and drug interaction, Selecting drug product source of supply

2. A national drug policy is an essential part of …

A Health Policy

B Fiscal Policy

C Marketing Policy

D Tax Policy

E Trade Policy

3. The basic principles of pharmaceutical provision of population according to NLP include:

A Information openness in providing pharmaceutical care;

B The availability of pharmaceutical care

C The market potential;

D Rational use of drugs;

E The quality of drugs and provision of pharmaceutical services.

4. Find and unite the correct information in the table:

■ Access		the quality, safety and efficacy of all medicines
■ Quality:		the promotion of therapeutically sound and cost-effective use of drugs by health professionals and consumers.
■ Rational use:		equitable availability and affordability of essential drugs

Chapter 4. THE INTERNATIONAL STANDARTS FOR PHARMACY

Pharmacist is one of the most regulating professions. All practicing pharmacists are obliged to ensure that the service they provide to every patient is of appropriate quality. In order to clarify and meet that obligation International Pharmaceutical Federation (FIP) in collaboration with other international organizations, including the World Health Organization (WHO) and other agencies sets global pharmacy standards through professional and scientific guidelines, policy statements and declarations.

Standards of practice are the requirements of professionalism in pharmacy practice respecting competency, ethical conduct and the application of pharmaceutical skills and knowledge. Standards are an important part in the measurement of quality of service to the consumer.

4.1. Good Laboratory Practice

Good Laboratory Practice generally refers to a system of management controls for laboratories and research organizations to ensure the consistency and reliability of results as outlined in the Organisation for Economic Co-operation and Development (OECD) Principles of GLP and national regulations.

GLP applies to non-clinical studies conducted for the assessment of the safety of chemicals to man, animals and the environment. The internationally accepted definition is as follows:

Good Laboratory Practice embodies a set of principles that provides a framework within which laboratory studies are planned, performed, monitored, recorded, reported and archived. These studies are undertaken to generate data by which the hazards and risks to users, consumers and third parties, including the environment, can be assessed for pharmaceuticals, agrochemicals, cosmetics, food and feed additives and contaminants, novel foods and biocides. GLP helps assure regulatory authorities that the data submitted are a true reflection of the results

obtained during the study and can therefore be relied upon when making risk/safety assessments.

Safe laboratory practice. It is important to be safe when working in a laboratory. Wear personal protective equipment (PPE) such as goggles, gloves or respiratory protection and be safe. Avoid exposure to hazardous material by planning all procedures before starting any laboratory work. The production of aerosols due to poor technique (squirting the last drop out of pipettes) and the spread of contamination due to spills is completely avoidable and especially important if you are handling infectious material, radiochemicals, carcinogens or highly toxic material.

4.2. Good Distribution Practice

Good Distribution Practice or GDP for wholesalers and distributors deals with the guidelines for the proper distribution of medicinal products for human use. GDP is a quality warranty system, which includes requirements for purchase, receiving, storage and export of drugs, intended for human consumption.

GDP regulates the division and movement of pharmaceutical products from the premises of the manufacturer of medicinal products, or another central point, to the end user thereof, or to an intermediate point by means of various transport methods, via various storage and/or health establishments.

4.3. Good Clinical Practice

Good Clinical Practice (GCP) for hospitals and clinicians conducting clinical studies on new drugs in humans is an international quality standard that is provided by International Conference on Harmonisation (ICH), an international body that defines standards, which governments can transpose into regulations for clinical trials involving human subjects.

Good Clinical Practice guidelines include protection of human rights as a subject in clinical trial. It also provides assurance of the safety and efficacy of the newly developed compounds.

Good Clinical Practice Guidelines include standards on how clinical trials should be conducted, define the roles and responsibilities of clinical trial sponsors, clinical research investigators, and monitors. In the pharmaceutical industry monitors are often called Clinical Research Associates.

4.4. Good Manufacturing Practice

Good Manufacturing Practice or **GMP** is a term that is recognized worldwide for the control and management of manufacturing and quality control testing of foods and pharmaceutical products.

Since sampling products will statistically only ensure that the samples themselves (and perhaps the areas adjacent to where the samples were taken) are suitable for use, and end-point testing relies on sampling, GMP takes the holistic approach of regulating the manufacturing and laboratory testing environment itself. An extremely important part of GMP is documentation of every aspect of the process, activities, and operations involved with drug and medical device manufacture. If the documentation showing how the product was made and tested (which enables traceability and, in the event of future problems, recall from the market) is not correct and in order, then the product does not meet the required specification and is considered contaminated (adulterated in the US). Additionally, GMP requires that all manufacturing and testing equipment have been qualified as suitable for use, and that all operational methodologies and procedures (such as manufacturing, cleaning, and analytical testing) utilized in the drug manufacturing process have been validated (according to predetermined specifications), to demonstrate that they can perform their purported function(s).

The World Health Organization (WHO) version of GMP is used by pharmaceutical regulators and the pharmaceutical industry in over one hundred countries worldwide, primarily in the developing world. The European Union's GMP (EU-GMP) enforces more compliance requirements than the WHO GMP, as does the Food and Drug Administration's version in the US. Similar GMPs are used in other

countries, with Australia, Canada, Japan, Singapore and others having highly developed/sophisticated GMP requirements. In the United Kingdom, the Medicines Act (1968) covers most aspects of GMP in what is commonly referred to as "The Orange Guide", because of the colour of its cover, is officially known as The Rules and Guidance for Pharmaceutical Manufacturers and Distributors.

4.5. Good Pharmaceutical Practice

In Tokyo September 5, 1993 the International Pharmaceutical Federation (FIP) adopted international guidelines for Good Pharmacy Practice. This document is intended to encourage national pharmaceutical organisations to focus the attention of pharmacists in the community and hospital pharmacy sector on developing the elements of the service they provide to meet changing circumstances.

Conscious of the need to help developing countries achieve GPP, the FIP Community Pharmacy Section Executive Committee established a working group to produce guidelines in this area in 1992. The paper, entitled “GPP in Developing Countries – Guidelines for Implementation”, was endorsed by the FIP CPS Executive Committee in September 1998.

These guidelines were developed as a reference to be used by national pharmaceutical organisations, governments, and international pharmaceutical organizations to set up nationally accepted standards of Good Pharmacy Practice.

The GPP Guidelines are based on the pharmaceutical care given by pharmacists. The guidelines recommend for national standards to be set:

- the promotion of health;
- the supply of medicines, medical devices, patient self-care;
- improving prescribing and medicine use by pharmacists’ activities.

These guidelines have been subsequently adapted and adopted in a wide number of developed countries. In certain cases, the national professional body has strived to adapt the guidelines and developed, in collaboration with the government, specific regulation/legislation on this matter.

Having realized the importance of continuing to increase awareness of GPP and stimulating its implementation, the FIP Bureau decided to request the BPP to focus on the theme and to develop a specific activity. They are the ones most frequently exposed to such products which may be inefficacious or toxic products, and which threaten to erode confidence in the health care system. It was for this reason that in May 1994 the Forty-seventh World Health Assembly, in adopting resolution WHA47.12 on the role of the pharmacist in support of the WHO revised drug strategy, drew attention to pharmacists' responsibilities in assuring the quality of the products they dispense.

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 involves activities both to secure good health and to avoid ill-health in the population. When ill-health is treated, it is necessary to assure quality in the process of using medicines in order to achieve maximum therapeutic benefit and avoid untoward side-effects. This presupposes the acceptance by pharmacists of shared responsibility with other professionals and with patients for the outcome of therapy. In recent years the term “pharmaceutical care” has established itself as a philosophy of practice, with the patient and the community as the primary beneficiaries of the pharmacist’s actions. The concept is particularly relevant to special groups such as the elderly, mothers and children, and chronically ill patients, as well as to the community as a whole in terms of, for example, cost containment. While the basic concepts of pharmaceutical care and good pharmacy practice are largely identical, it can be said that good pharmacy practice is the way to implement pharmaceutical care.

GPP is the practice of pharmacy that responds to the needs of the people who use the pharmacists’ services to provide optimal, evidence-based care. To support this practice it is essential that there be an established national framework of quality standards and guidelines.

Good pharmacy practice requires that a pharmacist's first concern in all settings is the welfare of patients.

Good pharmacy practice requires that the core of the pharmacy activity is the supply of medication and other health care products of assured quality, appropriate information and advice for the patient, and monitoring of the effects of use.

Good pharmacy practice requires that an integral part of the pharmacist's contribution is the promotion of rational and economic prescribing and of appropriate use of medicines.

Good Pharmacy Practice requires that the objective of each element of pharmacy service is relevant to the patient, is clearly defined and is effectively communicated to all those involved.

In satisfying these requirements, the following conditions are necessary:

Professionalism should be the main philosophy underlying practice, although it is accepted that economic factors are also important.

Pharmacists should have input into decisions about the use of medicines.

A system should exist that enables pharmacists to report adverse events, medication errors, defects in product quality or detection of counterfeit products. This reporting may include information about drug use supplied by patients or health professionals, either directly or through pharmacists. The ongoing relationship with other health professionals, particularly physicians, should be seen as a therapeutic partnership that involves mutual trust and confidence in all matters relating to pharmacotherapeutics. The relationship between pharmacists should be as colleagues seeking to improve pharmacy service, rather than as competitors. In reality, organizations, group practices and pharmacy managers should accept a share of responsibility for the definition, evaluation and improvement of quality. The pharmacist should be aware of essential medical and pharmaceutical information about each patient. Obtaining such information is made easier if the patient chooses to use only one pharmacy or if the patient's medication profile is available. The pharmacist needs independent, comprehensive, objective and current information

about therapeutics and medicines in use. Pharmacists in each practice setting should accept personal responsibility for maintaining and assessing their own competence throughout their professional working lives. Educational programs for entry to the profession should appropriately address both current and foreseeable future changes in pharmacy practice. National standards of good pharmacy practice should be specified and should be adhered to by practitioners.

Good pharmacy practice involves four main groups of activities, namely:

- activities associated with the promotion of good health, the avoidance of ill-health and the achievement of health objectives;
- activities associated with the supply and use of medicines and of items for the administration of medicines or for other aspects of treatment (these activities may be undertaken in the pharmacy, in an institution or in a homecare setting);
- activities associated with self-care, including advice about and, where appropriate, the supply of a medicine or other treatment for symptoms of ailments that lend themselves to self-treatment;
- activities associated with influencing the prescribing and use of medicines.

In addition to these groups of activities *good pharmacy practice also encompasses*:

- establishment of arrangements with other health professional communities for health promotion activities at population level, including minimization of the abuse and misuse of medicines;
- professional assessment of promotional materials for medicines and other products associated with health care;
- dissemination of evaluated information about medicines and various aspects of health care;
- involvement in all stages of clinical trials.

For each of the four main elements of good pharmacy practice, national standards should be established in relation to processes and facilities (table 4.1).

Table 4.1

	National standards are needed for:
Promotion of health and prevention of ill-health.	♦ facilities for confidential conversation that cannot be overheard by others; ♦ provision of general advice on health matters; ♦ involvement of personnel in briefings for specific campaigns to ensure coordination of effort and consistency of advice; ♦ quality assurance of equipment used and advice given in diagnostic testing.
Supply and use of prescribed medicines and other health care products **1.** Reception of the prescription and confirmation of the integrity of the communication **2.** Assessment of the prescription by the pharmacist. The term "national standards" includes laws, regulations, standards, ordinances or other requirements enacted or promulgated by an official body at any level of government, as well as guidelines, recommendations or other pronouncements of professional organizations of pharmacy. This activity involves therapeutic aspects (pharmaceutical and pharmacological), consideration of appropriateness for the individual, and social, legal and economic aspects. **3.** Assembly of the prescribed items. **4.** Advice to ensure that the patient or carer receives and understands sufficient written and oral information to derive maximum benefit from the treatment **5.** Following up the effect of prescribed treatments **6.** Documentation of professional activities	♦ facilities; ♦ procedure; ♦ personnel ♦ information sources; ♦ competence of personnel; ♦ medication records. ♦ sources of supply of medicines and other items; ♦ manufacture of medicines; ♦ storage; ♦ condition at time of supply to the patient; ♦ personnel involved; ♦ equipment required; ♦ facilities and workplace required; ♦ preparation and quality assurance of extemporaneous preparations; ♦ disposal of unused pharmaceutical products and pharmaceutical waste. ♦ facilities for confidential conversation that cannot be overheard by others; ♦ information sources; ♦ procedures to be followed and the appropriate documentation of these procedures; ♦ competence of personnel involved. ♦ procedure to be followed in regular, systematic evaluation of progress or outcomes of treatment for individual patients or for groups of patients; ♦ access to necessary monitoring equipment and facilities; ♦ quality assurance of monitoring facilities. ♦ recording professional activities and pertinent data in a manner that allows access to comprehensive information; ♦ procedures for self-assessment of professional activities and quality assurance.

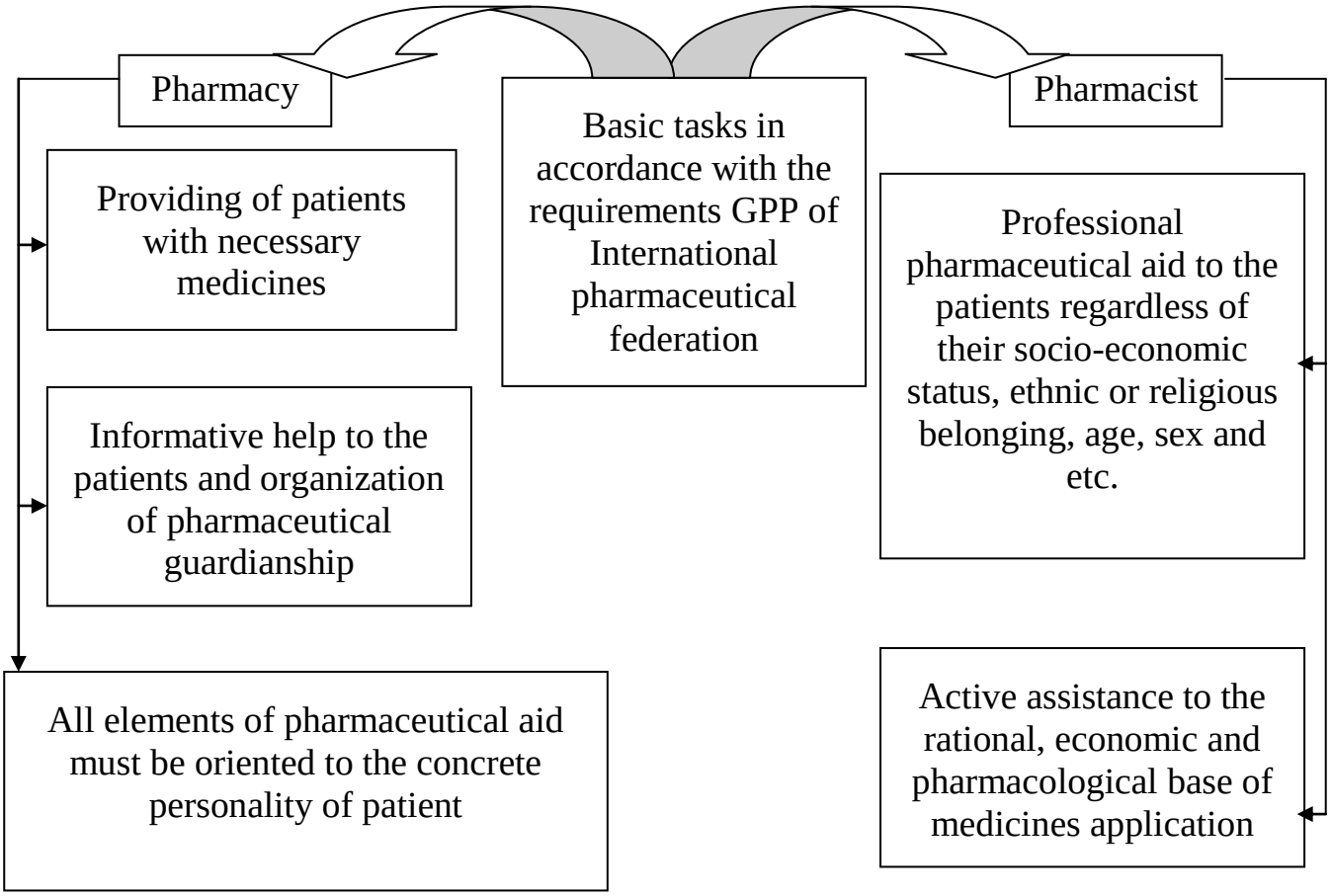
Cont. table 4.1.

Self-care	♦ facilities for confidential conversation that cannot be overheard by others; ♦ qualifications of personnel to be involved; ♦ the ways of correctly assessing need, (e.g. finding out who has the problem, what the symptoms are, how long the condition has existed, what action has already been taken, which medicines are already being taken); ♦ efficacy and safety of products recommended; ♦ timing of referral to the medical practitioner and methods of follow-up.
Influencing prescribing and medicine use	♦ quality of prescribing data provided to the pharmacist; ♦ the preparation of formularies on medicines; ♦ contacts with physicians on individual prescribing; ♦ evaluation of data on the use of medicines in medical and pharmaceutical practices; ♦ assessment of promotional materials; ♦ dissemination of evaluated information within a formal network; ♦ educational programs for health professionals; ♦ reference sources available to the pharmacist; ♦ confidentiality of data relating to individual patients; ♦ reporting of adverse events, medication errors, defects in product quality ♦ and detection of counterfeit products.

These standards should be promoted among members of the profession.

Pharmacists have a professional responsibility to document practice experience and activities and to conduct and/or participate in pharmacy practice research and therapy research. Specific standards of good pharmacy practice can be developed only within the framework of a national organization. These guidelines are recommended as a set of professional goals in the interest of the patients or customers in the pharmacy. Responsibility for moving the project forward will rest with each national pharmaceutical organization. Achieving specific standards of good pharmacy practice for each nation within these guidelines may require considerable time and effort. As health professionals, pharmacists have a duty to begin the process without delay.

Main tasks of pharmacy and pharmacist in accordance with the requirements GPP is shown in scheme 4.1.



Cheme 4.1. Main tasks of pharmacy and pharmacist in accordance with the requirements GPP

Thus, all international standarts describes a set of principles and procedures that when followed helps ensure that therapeutic goods and services are of high quality.

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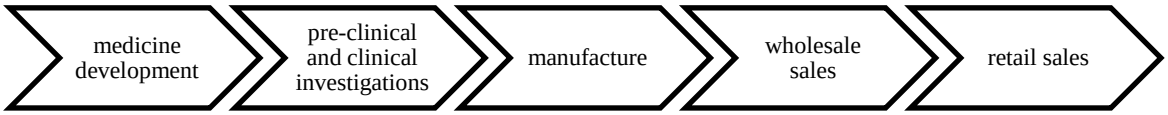
Review questions

1. What International standards that regulate pharmaceutical activity do you know? Give a short definition (GLP, GCP, GMP, GDP, GPP).
2. What are the definition, targets and elements of the Good pharmacy practice (GPP)?
3. What are four basic directions of the guidance GPP?

Check Your Understanding

1. How the international standarts interrelated with different stages at the long path of the drug development (from idea to drug)?



2. The guidelines recommend for national standards to be set:

A the promotion of health;

B advertising and marketing of the drugs;

C the supply of medicines, medical devices, patient self-care;

D improving prescribing and medicine use by pharmacists' activities;

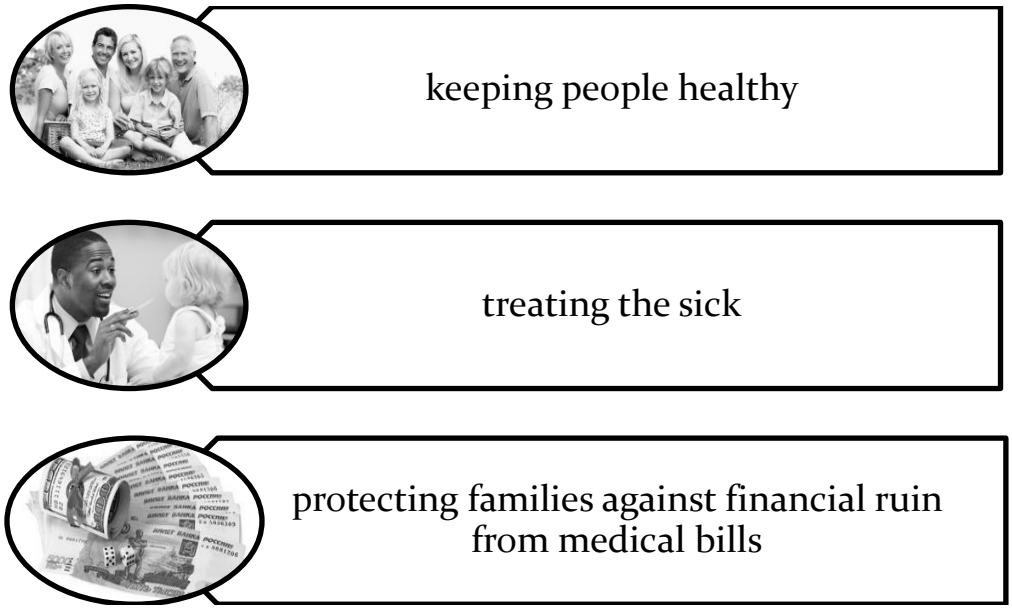
E providing of the medical insurance and reimbursement for the population.

3. Align the terms of their definition:

1	Good Laboratory Practice (GLP)	**A**	is recognized worldwide for the control and management of manufacturing and quality control testing of foods and pharmaceutical products.
2	Good Clinical Practice (GCP)	**B**	generally refers to a system of management controls for laboratories and research organizations to ensure the consistency and reliability of results as outlined in the OECD Principles of GLP and national regulations.
3	Good Manufacturing Practice (GMP)	**C**	includes requirements for purchase, receiving, storage and export of drugs, intended for human consumption.
4	Good Pharmaceutical Practice (GPP)	**D**	includes protection of human rights as a subject in clinical trial. It also provides assurance of the safety and efficacy of the newly developed compounds.
5	Good Distribution Practice (GDP)	**E**	responds to the needs of the people who use the pharmacists' services to provide optimal, evidence-based care. The standard defines the main problem for pharmacies and pharmacists in general.

Chapter 5. GENERAL PRINCIPLES OF HEALTH AND PHARMACEUTICAL CARE SYSTEM FUNCTIONING

Health care is a fundamental human right. But it cost money! How the patient will pay for it? Financing is one of the central problem of the health care systems of the different countries. There are about 200 countries on our planet, and each country devises its own set of arrangements for meeting the three basic goals of a health care system (Scheme 5.1.).

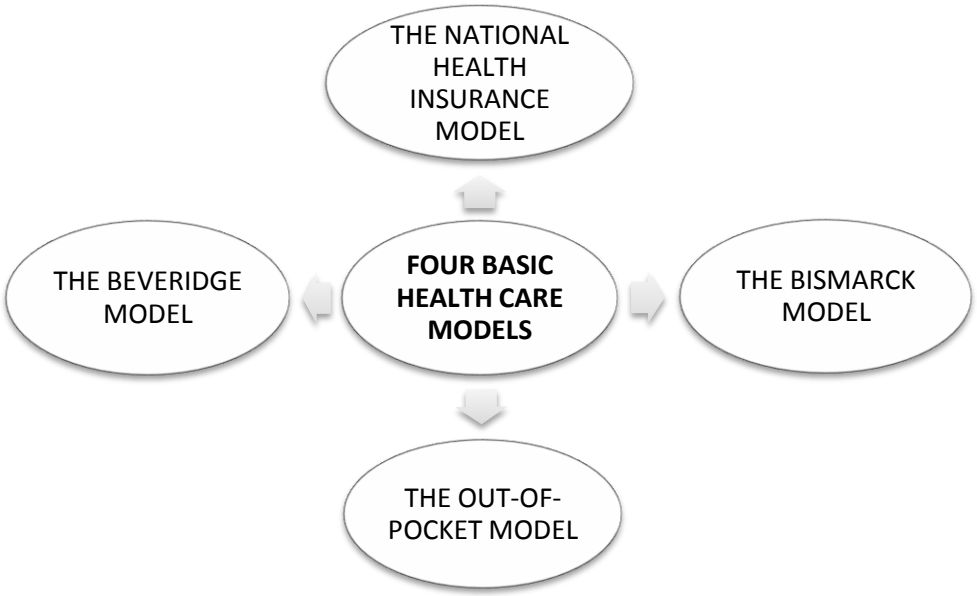


Scheme 5.1. The basic goals of a health care system

Each nation's health care system is a reflection of its:

- History
- Politics
- Economy
- National values

They all vary to some degree. However, they all share common principles of health care system functioning. There are four basic health care models around the world (Scheme 5.2).



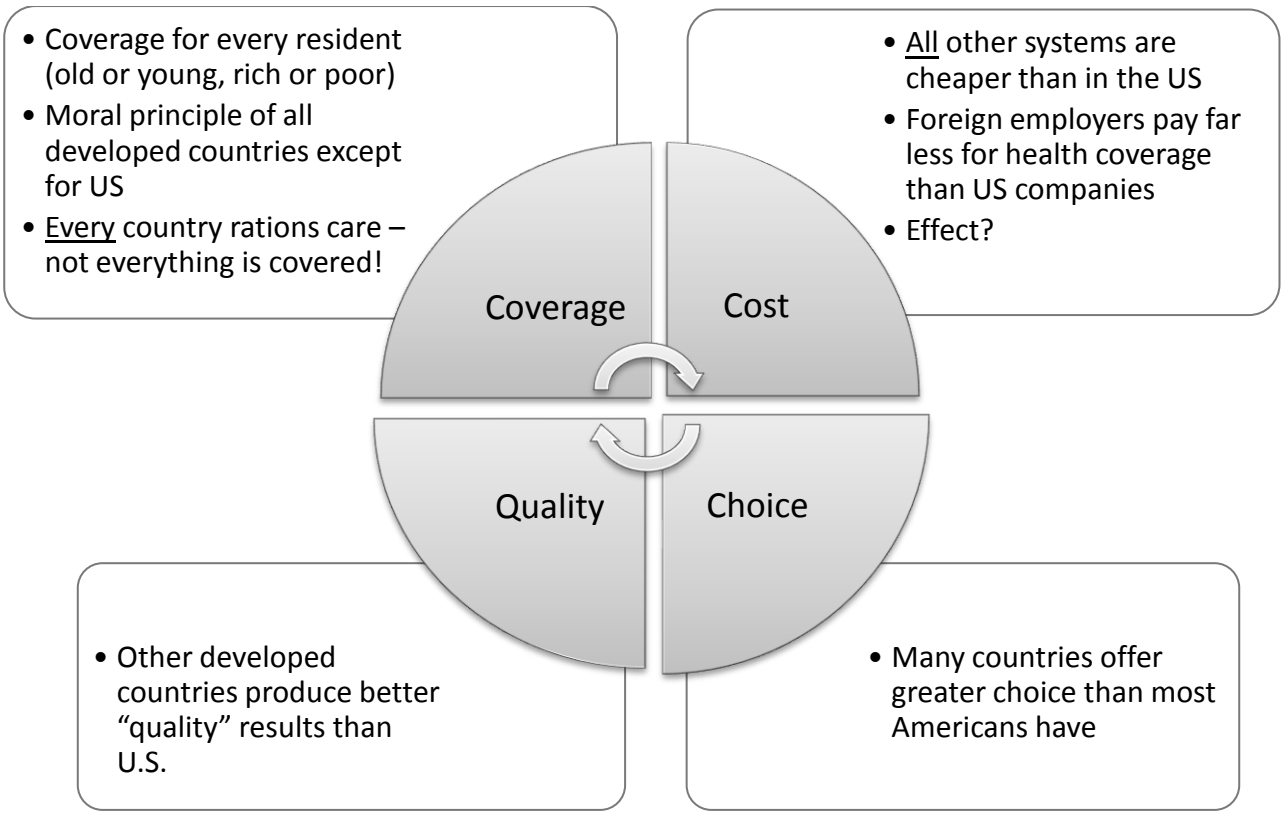
Scheme 5.2. Health Care Systems - Four Basic Models

The geographic location and the main characteristics of the models are shown in table 5.1 and scheme 5.3.

Table 5.1

The comparable characteristics of Four Basic Models of Health Care Systems

Model	**The Beveridge Model**	**The Bismarck Model**	**The national health insurance model**	**The out-of-pocket model**
Used in countries	Great Britain, Spain, Denmark, Sweden, Finland, Greece, Italy, Portugal and New Zealand	Germany, Japan, France, Belgium, Switzerland, Japan, and Latin America	Canada, Taiwan, South Korea	Rural regions of Africa, India, China, and South America
Characteristics	Healthcare is provided and financed by the **government**, through tax payments. There are no medical bills. Medical treatment is a public service. Providers can be government employees. Lows costs b/c the government controls costs as the **sole payer.**	Providers and payers are private. Private insurance plans – financed jointly by employers and employees through payroll deduction. The plans cover everyone and do not make a profit. Tight regulation of medical services and fees (cost control)	Providers are private. Payer is a government-run insurance program that every citizen pays into; National insurance collects monthly premiums and pays medical bills. Can control costs by: (1) limiting the medical services they will pay for or (2) making patients wait to be treated	Only the rich get medical care; the poor stay sick or die; most medical care is paid for by the patient, out-of-pocket; no insurance or government plan
Financing	public	mixed	mixed	private



Scheme 5.3. Common principles of all models

5.1.The Beveridge Model

Named after William Beveridge, the daring social reformer who designed Britain's National Health Service. In this system, health care is provided and financed by the government through tax payments, just like the police force or the public library and called state-budgetary.

Many, but not all, hospitals and clinics are owned by the government; some doctors are government employees, but there are also private doctors who collect their fees from the government. In Britain, you never get a doctor bill. These systems tend to have low costs per capita, because the government, as the sole payer, controls what doctors can do and what they can charge. Countries using the Beveridge plan or variations on it include its birthplace Great Britain, Spain, Denmark, Sweden, Finland, Greece, Italy, Portugal and New Zealand. Hong Kong still has its own Beveridge-style health care, because the populace simply refused to give it up when the Chinese took over that former British colony in 1997. Cuba represents the

extreme application of the Beveridge approach; it is probably the world's purest example of total government control.

In this system, the health care is provided and financed by the government through taxes. There are no medical bills for patients. Medical care is treated as a public service like public education or the fire department. Hospitals are owned by the government and many doctors who are specialists are employees of the government. Most primary care doctors are private practitioners who are paid by the government and receive bonuses for keeping their patients as healthy as possible. England and Spain use this model. In the United States the Veterans Administration is an example of this socialized medicine model.

Basic advantages of Beveridge model:

- hundred-per-cent defense of population in case of illness or loss of capacity;
- providing of social stability in the company due to the complete compensation of cost of medical treatment from the state budget

5.2. The Bismarck Model

Named for the Prussian Chancellor Otto von Bismarck, who invented the welfare state as part of the unification of Germany in the 19th century. Despite its European heritage, this system of providing health care would look fairly familiar to Americans. It uses an insurance system -- the insurers are called "sickness funds" -- usually financed jointly by employers and employees through payroll deduction.

Unlike the U.S. insurance industry, though, Bismarck-type health insurance plans have to cover everybody, and they don't make a profit. Doctors and hospitals tend to be private in Bismarck countries; Japan has more private hospitals than the U.S. Although this is a multi-payer model -- Germany has about 240 different funds -- tight regulation gives government much of the cost-control clout that the single-payer Beveridge Model provides.

The Bismarck model is found in Germany, of course, and France, Belgium, the Netherlands, Japan, Switzerland, and, to a degree, in Latin America.

Employers and employees fund national health insurance through compulsory payroll taxes. Insurance companies are private entities but are required to be non-profit and are heavily regulated especially with respect to fees and medical services. They are not allowed to exclude people for pre-existing conditions nor drop anyone if they develop an illness. Health providers and hospitals are largely private. Patients pay small co-pays for their health care. Patients can buy secondary insurance coverage for services not provided by through the national health system such as a private hospital room. In this model, there are many private insurance companies therefore it is referred to as a multi-payer system. Germany and Switzerland use this model.

Basic advantages of Bismarck model:

- high degree of defense of population regardless of material and social status of citizens and members of their families in the society;
- providing of social stability in the company due to the hundred-per-cent providing of population by the insurance defense in case of illness or loss of capacity;
- support by the state of private sector of medical and pharmaceutical services with the target of forming of healthy competitive environment at the market of medical insurance;
- financial openness of model, possibility of bringing in of additional sources of financing.

5.3. The National Health Insurance Model

This system has elements of both Beveridge and Bismarck. It uses private-sector providers, but payment comes from a government-run insurance program that every citizen pays into. Since there's no need for marketing, no financial motive to deny claims and no profit, these universal insurance programs tend to be cheaper and much simpler administratively than American-style for-profit insurance.

The single payer tends to have considerable market power to negotiate for lower prices; Canada's system, for example, has negotiated such low prices from pharmaceutical companies that Americans have spurned their own drug stores to buy pills north of the border. National Health Insurance plans also control costs by limiting the medical services they will pay for, or by making patients wait to be treated.

The classic NHI system is found in Canada, but some newly industrialized countries -- Taiwan and South Korea, for example -- have also adopted the NHI model.

5.4.The Out-of-Pocket Model

Single-Payer Model

In a single payer model, the providers of health care are largely private. There is one payer, the government. The national insurance plan collects the money and pays the medical bills. There are usually no co-pays or deductibles. Medicare is an example of a single payer system. Health care is provider by private doctors in private facilities and the majority of the medical bill is paid by the government. Canada and Taiwan use this model.

Only the developed, industrialized countries -- perhaps 40 of the world's 200 countries -- have established health care systems. Most of the nations on the planet are too poor and too disorganized to provide any kind of mass medical care. The basic rule in such countries is that the rich get medical care; the poor stay sick or die.

In rural regions of Africa, India, China and South America, hundreds of millions of people go their whole lives without ever seeing a doctor. They may have access, though, to a village healer using home-brewed remedies that may or not be effective against disease.

In the poor world, patients can sometimes scratch together enough money to pay a doctor bill; otherwise, they pay in potatoes or goat's milk or child care or whatever else they may have to give. If they have nothing, they don't get medical care.

These four models should be fairly easy for Americans to understand because we have elements of all of them in our fragmented national health care apparatus.

When it comes to treating veterans, we're Britain or Cuba. For Americans over the age of 65 on Medicare, we're Canada. For working Americans who get insurance on the job, we're Germany.

For the 15 percent of the population who have no health insurance, the United States is Cambodia or Burkina Faso or rural India, with access to a doctor available if you can pay the bill out-of-pocket at the time of treatment or if you're sick enough to be admitted to the emergency ward at the public hospital.

The United States is unlike every other country because it maintains so many separate systems for separate classes of people. All the other countries have settled on one model for everybody. This is much simpler than the U.S. system; it's fairer and cheaper, too.

Basic advantages of the private (market) model:

- high quality of medical and pharmaceutical services, the population is getting in the system of private money insurances;
- financial and legal independence of subjects of insurance relations;
- possibility of free market development of medical and pharmaceutical services;
- financial openness and „mobility" of model of medical insurance.

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Review questions

1. How can you idenlify the basic tasks and functions of medical insurance in the modern market conditions?

2. What basic models of healthcare do you know? Characterise them.

3. What are the advantages of different kinds of the medical insurance?

4. Call the common priunciples for all models of healthcare system.

5. What is the reimbursement and how is it functioning?

6. Explain the terms «insurance», «insures», «insurers», «insured persons».

Check Your Understanding

1. The medical insurance executes such functions:
- *a.* stimulant
- *b.* risk
- *c.* accumulation
- *d.* registration
- *e.* compensative

2. The subjects of obligatory and voluntarily medical insurance are:
- *a.* insures
- *b.* insurers
- *c.* insured citizens
- *d.* legal entities, giving medical and pharmaceutical assistance (services)
- *e.* State inspection on the control of the quality LS

3. Basic principles of voluntarily medical insurance are:
- *a.* insurance interest
- *b.* maximal trust between the subjects of insurance activity
- *c.* compensation to the insured person within the framework of the inflicted harm
- *d.* free choice of insurer and type of insurance
- *e.* insurance risk
- *f.* obligatory
- *g.* social solidarity

4. The payments, which are carried out by insurer to the insured person according to the conditions of the agreement of insurance, are called...
- *a.* insurance bonuses
- *b.* insurance payments

5. Legal and physical entities, which pay insurance payments are called...
- *a.* insures
- *b.* insurers
- *c.* insurance companies
- *d.* insurance brokers
- *e.* insurance agents

Chapter 6. ORGANISATIONAL PRINCIPLES OF PHARMACY WORK

6.1. Chemist shop as organization of Health care system

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 sales of medicines and other pharmacy assortment. Its 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***); sales 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***).

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. The many kinds of drugs people use can be classified in several ways. For example, they can be grouped according to their form, such as shown in the table 1. 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. One more classification

that is certainly used at chemists devides them for two groups: prescription and non-prescription drugs (table 6.1).

Table 6.1

<table>
<tr><td colspan="5">DRUGS</td></tr>
<tr><td colspan="2">PRESCRIPTION</td><td colspan="3">NON- PRESCRIPTION</td></tr>
<tr><td>READY-MADE</td><td>EXTEMPOREOUS</td><td>READY-MADE</td><td>THINGS FOR MEDICAL CARE</td><td>PLANT DRUGS</td></tr>
<tr><td colspan="3">Tablets, capsules, pills, inhalation products, gels, powders, ointment, suppositories, liquids such as syrupes, solutions, suspensions, mixtures, drops, tinctures and decoctines ets.</td><td colspan="2">thermometers, cups, hot-water bottles, bandages, cotton and gauze etc.</td></tr>
</table>

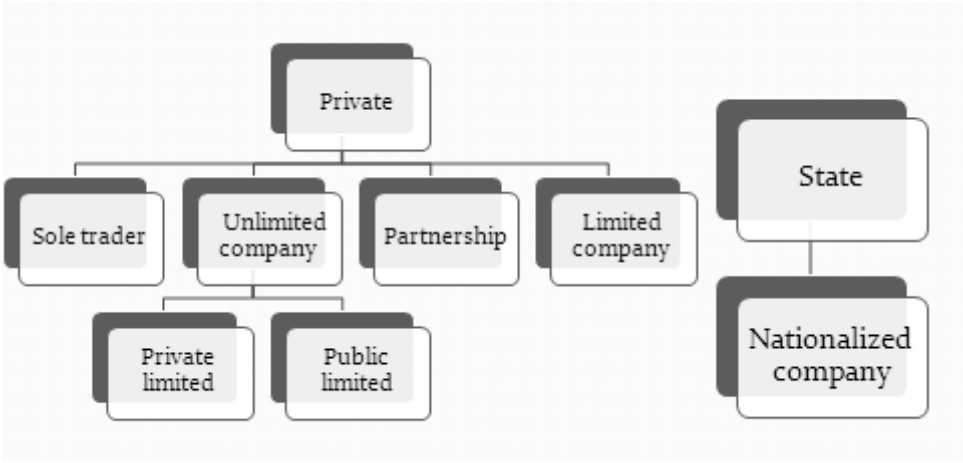
NONPRESCRIPTION drugs such as aspirin and some cough medicines are considered safe enough to be sold over the counter that is any drug or product not requiring a prescription for sale. *PRESCRIPTION* is an order from a practitioner authorizing the dispensing of a drug. Prescription drugs include antibiotics,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

The chemists' can classified depends on different characteristics:

- the place where it is situated: city, town, country;
- the category of population served by it: heriatric, children, for mother and child;
- the kinds of medicines sold there: homeopatic, the chemists' of medical herb;
- the category of patients served: antydiabetic, dermatologic;
- the property and etc.

Pharmacy may be state and communal, private and with the collective pattern of ownership (according to the owner) as shown on scheme 2. *On a form the management and to the sources of financing distinguish:* self-supporting, which

independently form profits as difference between the cost of sales and purchase cost of commodity; the state budget pharmacies belonging to the organizational clinic structure and is financed directly from the state budget. *In obedience to territorial subordination* city and rural pharmacies *are determined. To directions of activity* of pharmacy distribute on: retail, which carry out only the retail medicine sales, and hospital, interhospital, self-supporting, the state budget pharmacies, which serve hospital, nursery schools, schools, sanatoriums and other organizations and enterprises, on the cashless form of calculation. Hospital and interhospital pharmacies are named abroad „hospital pharmacies". *On the medicine assortment, realized to the users,* pharmacies are divided into homoeopathic, preparations of vegetable origin, hormonal preparations, ready made drug, general type – pharmacy, in the assortment of which preparations of different pharmaceutical firms and pharmacotherapeutical groups. *On a functional index* pharmacies are divided into productions, which are engaged in the medicine making on the individual recipes of doctors and unproductive, carrying out exceptional sales of industrial production medicine. *In obedience to the groups of patients and categories of population*, which are mainly served by pharmacies, the specialized pharmacies are determined, for example, geriatrics, „Mother and child" and general type.



Scheme 6.1. The classification of the pharmacy according the property

The proprietor is the sole owner of a business and has full control of it. He is personally liable for all business debts, i.e. he carries an unlimited liability. This

means that if his business fails, not only business assets are to be sold to cover outstanding debt, but also the owner's personal property.

Partners jointly own a business and each partner is personally liable for the firm's debt. If any of the partners have limited liability (in a limited partnership) in a worse-case scenario they can lose only the capital they invested in the business.

A limited company is the most common form of business. A linited company is a legal entity that is separated from shareholders and directors. The shareholders are not liable for the company's debts beyond the amount remaining unpaid on the shares they hold or guaranteed to a third party.

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, and drug 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 decoctina as well as drops, suppositories ets.

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.

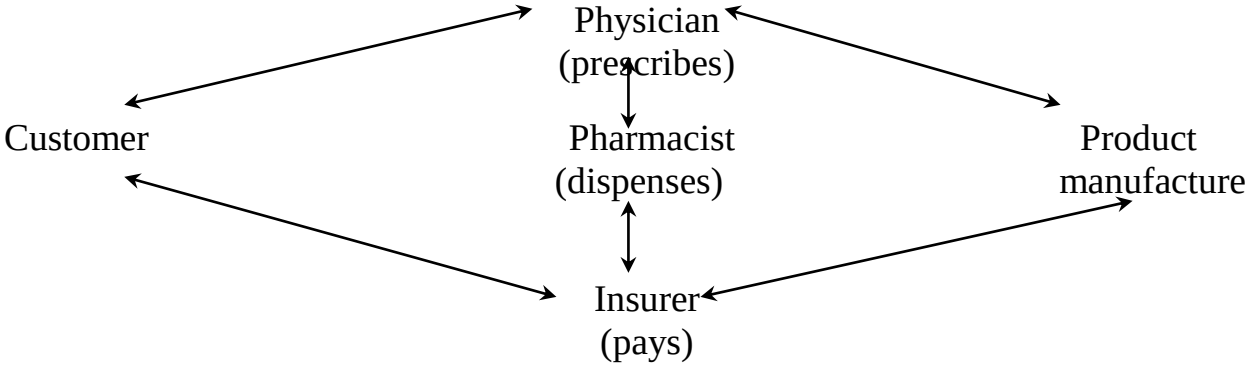
The aims of drugs store department are to organise: the provision of chemists with different drugs in time, the reception of the products, the storing of drugs depends on their storage conditions and the provision of all departments of chemists with everything they need.

The 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, compouning, and dispensing of drugs. Also it may have an asseptic 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.

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 6.2.



Scheme 6.2. 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 personel 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 honour 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.

6.2. 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.

Philosophy of 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.

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.

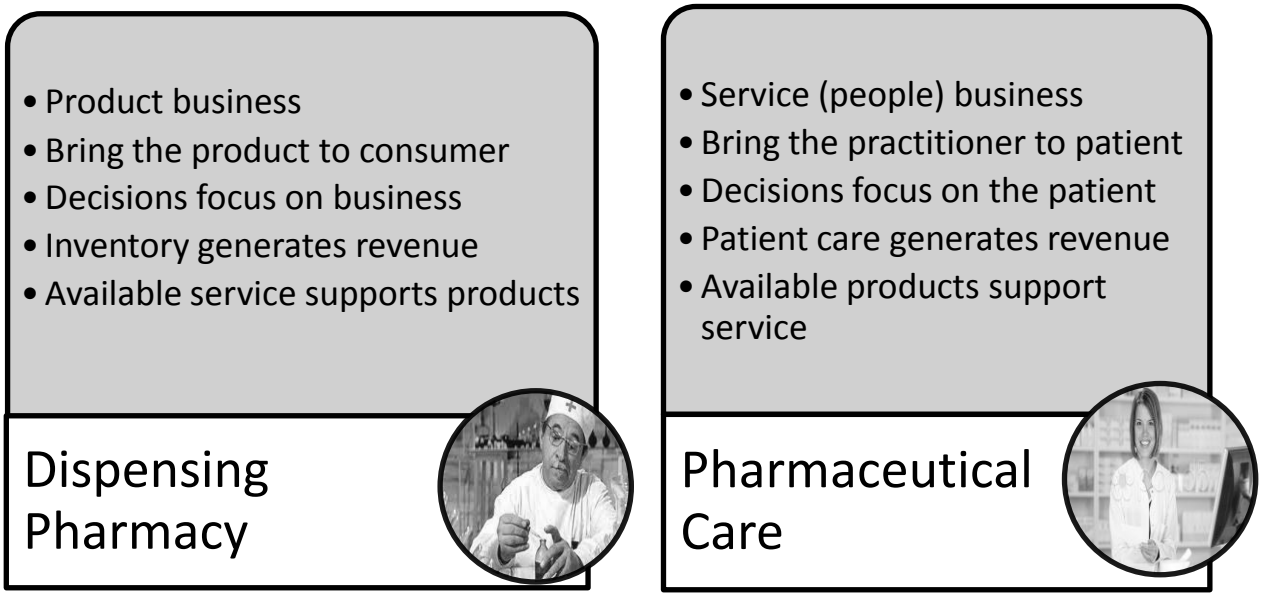
Pharmaceutical care is a necessary element of health care that should be integrated with other elements. Pharmaceutical care is, however, provided for the direct benefit of the patient, and the pharmacist is responsible directly to the patient for the quality of that care. The fundamental relationship 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.

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.

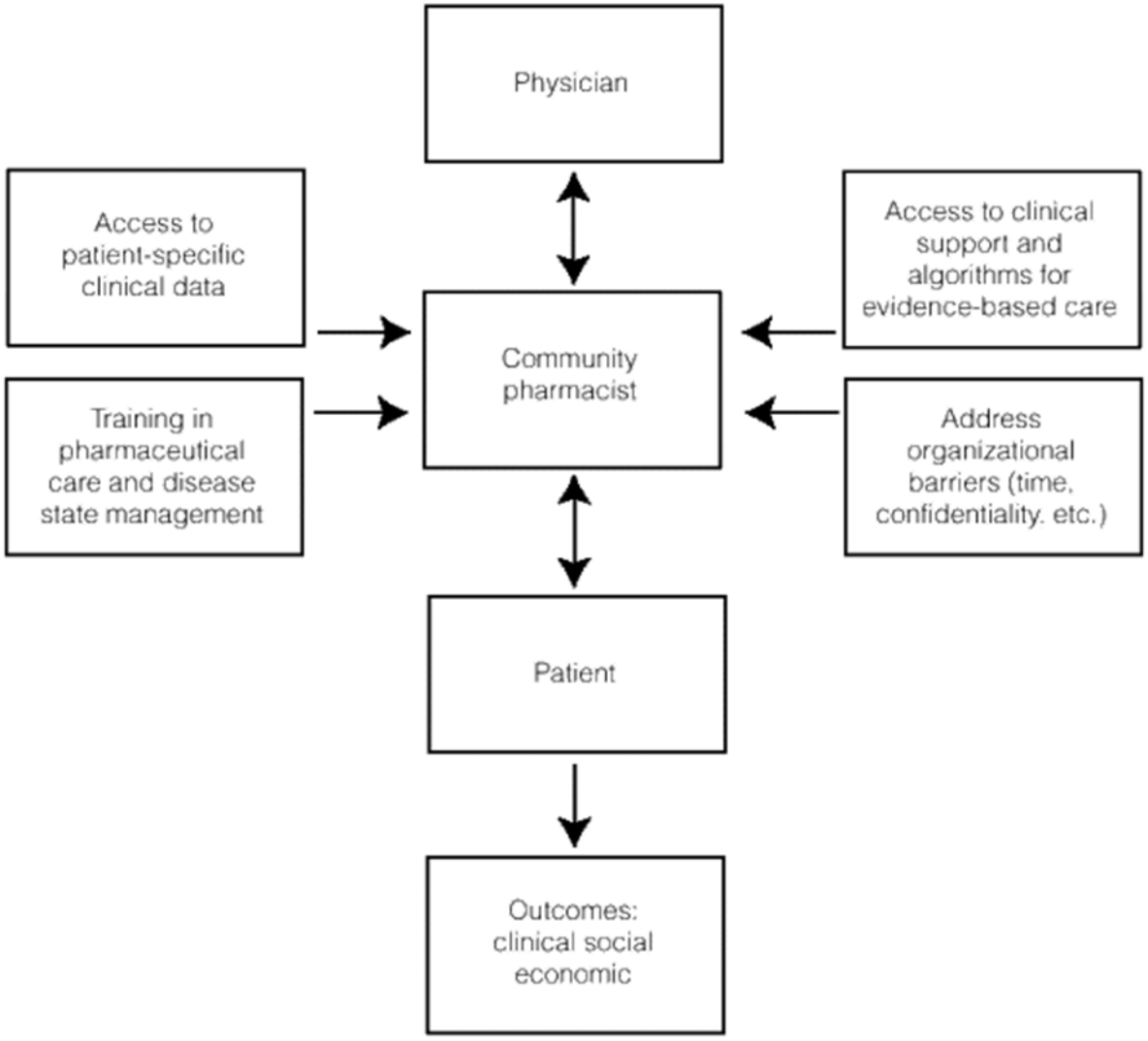
Pharmaceutical Care emphasises that pharmacists adopt the role of a carer for patients within their practice (Scheme 6.3.). They put their knowledge, skills and professionalism to work to help prevent and resolve patient's drug-related problems within the operational structure of the Health Service. This involves more than a knowledge of drugs and diseases because practising Pharmaceutical Care means trying to ensure that each aspect of health care which can have an impact on medication use is delivered in an optimal way.



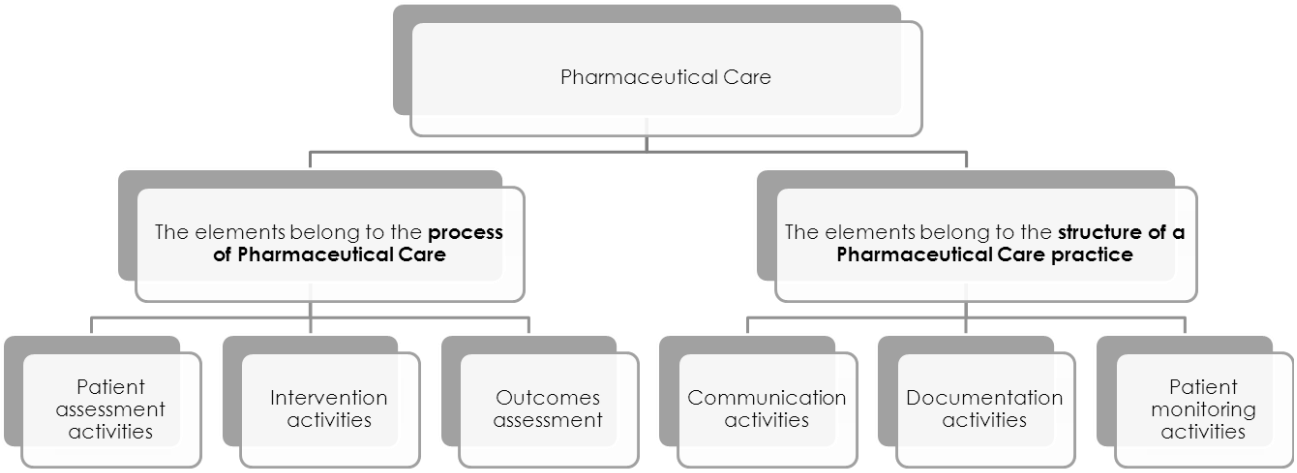
Scheme 6.3. Differences in the approaches to pharmacy practice

And furthermore, since each patient has different needs, wants and attitudes, every patient's pharmaceutical care plan must account for those differences. An analytical mind-set and an insistence on standards and verification are central to the laboratory-based sciences in the pharmacy curriculum. They are equally important in the practice of Pharmaceutical Care.

To provide Pharmaceutical Care, pharmacists take on the responsibility of the patient's care and aim to improve the patient's quality of life. This is a departure from previous practice. It requires that the pharmacist focus on setting and monitoring outcomes. It means that pharmacists must be prepared to provide long term continuing care whenever it is needed. It necessitates that pharmacists change from being reactive to becoming proactive in order to prevent as well as solve problems. It draws pharmacists into a co-operative working relationship with other Health Care professionals (Scheme 6.4).



Scheme 6.4.Relation of Pharmaceutical Care to other fields and activities within Pharmacy Practice



Scheme 6.5. The elements of the Pharmaceutical Care

Three elements belong to the process of Pharmaceutical Care (Scheme 6.5) and a list of specific skills (not in order of their importance) is set out:

1. Patient assessment activities include:

a.Identifying drug related problems (medication history)

b. Identifying disease related problems (medical history)

c.Identifying opportunities in health promotion and ill-health prevention (social/family history)

d. Characterising of patient expectations

2. Intervention activities include:

a.Selection of appropriate intervention together with patient

b. Selection of appropriate intervention together with other health care providers

c.Selection of advise about healthy lifestyles

d. Rationalisation of individual treatments (depending of social and legal aspects)

e.Devising treatment plan

f. Agreeing specific outcomes g. Agreeing patient education

g. Agreeing patient monitoring plans

3. Outcomes assessment:

a.Change of clinical data or change of symptoms

b. Health Related Quality of Life

b. Pharmaco-economical factors

c.Pharmaco-epidemiological factors

d. Check against original Pharmaceutical Care plans

Three elements belong to the structure of a Pharmaceutical Care practice (in figure 3 the bars):

4. Communication activities include:

a.Communication with patients

b. Communication with other Health Care professionals c. Communication with "informal" providers of care

5. Documentation activities include:

a.Pharmaceutical Care records (electronically or on paper) including

i. Medication history (including all dispensed drug over a longer period of time)

ii. Medical history (obtained from physicians or/and the patient)

iii.Social and family history

iv.Communication records

v. Laboratory results

b. A Pharmaceutical Care plan for the individual patient

6. Patient monitoring activities include:

a.Dealing with compliance with medication regimens and lifestyles

b. Dealing with compliance with treatment plan

b. Dealing with clinical data

c.Scheduling patient contacts

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.

6.4. 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.

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.

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.

6.5. Requirements to the pharmacies and organization of pharmaceutical care

Retail sale of medicines is carried out only by pharmacies and their structural subdivisions (pharmacy points). International experience show - for increasing of availability of medicines to the population under certain conditions, there should be exceptions. Thus, in Ukraine in rural areas, in the absence of pharmacy (pharmacy points) retail sale of medicines can be carried by paramedic, health posts, village and district hospitals and dispensaries under agreements entered with an entity that has a license, provided that the sales will be carried by the person with medical education.

Pharmacies have the right to buy and sell except medicines related products on the list adopted by the Ministry of Health such as medical products, including optics; disinfectants; personal care items (oral care products, means for and after shaving,

soaps, shampoos, etc.); natural and artificial mineral waters; special nutritional products (dietary, preventive foods and dietary supplements, baby food and nutrition for athletes); therapeutic cosmetics (creams, shampoos, lotions etc.); repellents.

All pharmacies, regardless of ownership, should comply with licensing conditions and requirements of the sanitary-epidemiological order of pharmacies, as defined by the applicable regulations, namely:

- to ensure presence of all the necessary apartments, equipment and machinery for the proper storage and sale of medicines;
- to have the required number of staff with the qualification requirements;
- to create the necessary conditions for accessibility of persons with disabilities to pharmacies;
- to comply with the storage conditions specified by the manufacturer of medicinal products;
- to have service information on a license (copy of license), address and telephone number of the entity owners, addresses and telephone numbers of government control organizations as well as book “of reviews and suggestions” in the hall for visitors;
- to ensure availability of the minimum assortment of medicines into the pharmacy defined by MOH;
- to comply with legal requirements to ensure the quality of drugs and have a plan for immediate action to remove medication from sale;
- to ensure the storage of medicines;
- to keep for at least three years the documents confirming the purchase, indicating name, date, dosage form, quantity, batch and expiry date of medicines, the supplier and the details of its license;
- to determine an “authorized person” who has completed higher pharmaceutical education and professional experience not less than 2 years;

- to provide for each apartment registration and control of temperature and relative humidity, the serviceability of all measuring instruments and carry out their regular metrological verification.

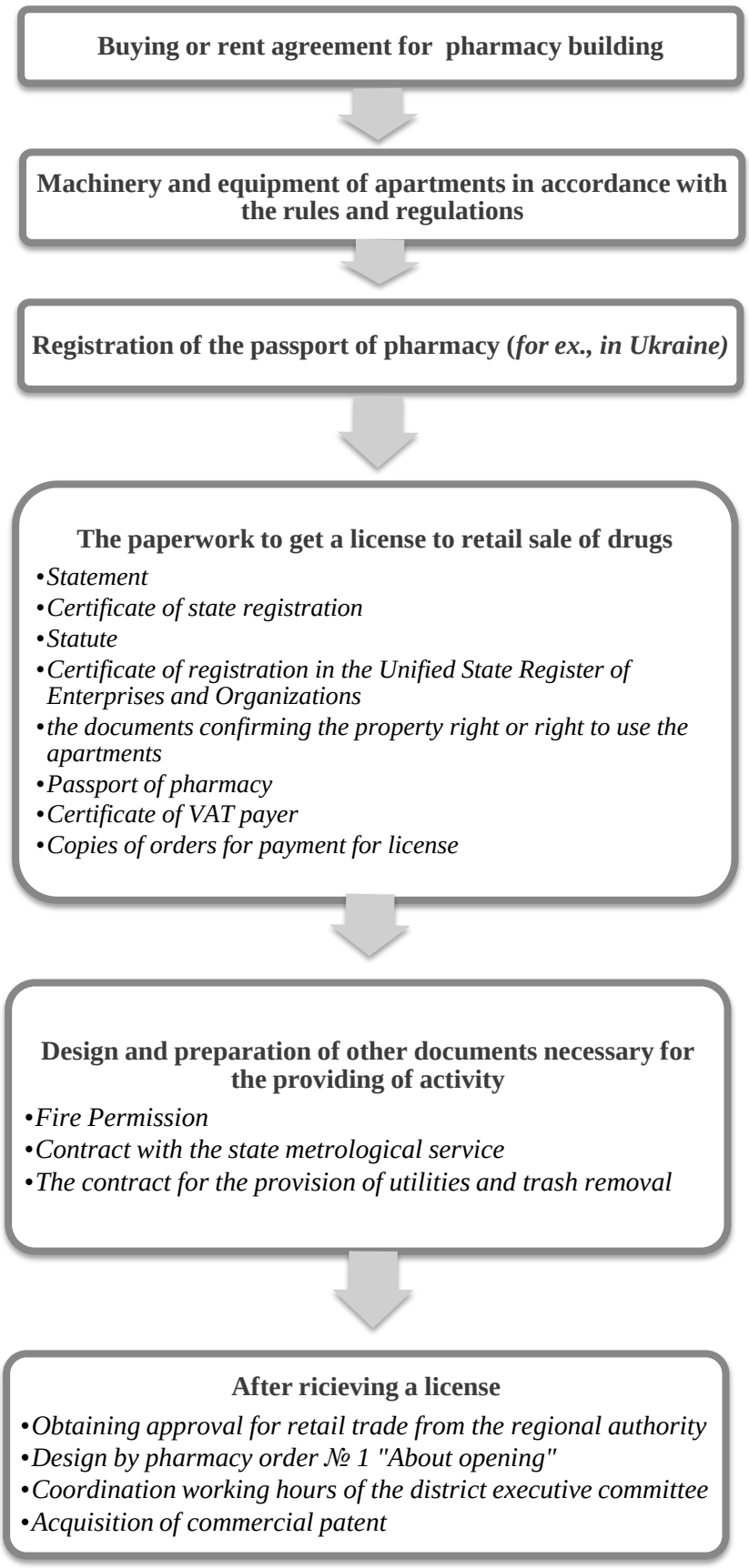
Pharmacy should be placed in an isolated building with a separate entrance. According to the legislation of some countries area of pharmacies is regulated. In Ukraine, for example, the total minimum area of pharmacy should be:

- for pharmacies realized ready-made medicines - not less than 50 square meters (the area of hall for visitors - not less than 18 sq. m.) ;
- for pharmacies located in rural areas - at least 40 square meters;
- for pharmacies compounded medicines it is necessary to have all required facilities for retail sale of medicines and facilities for the compounding of medicines, staff and area are determined by the Ministry of Health.

An average pharmacy must be dedicated with *hall for visitors*. It is allowed to provide activity without *hall for visitors* only for hospitals and interhospitals pharmacies that compound drugs and have no sales directly to the population. H*all for visitors* is equipped with devices to protect pharmacists from direct droplet infection. It is allowed to equipped the H*all for visitors* with free access of population to the OTC-drugs and related products in the presence of special consultants (pharmacist).

The pharmacy building must be equipped with a signboard indicating the name of the enterprise ("Pharmacy", "Pharmacy point"), but not advertising. In some countries for pharmacies and pharmacy points is required information indicating the address of the nearest (24-houres work) pharmacy. Pharmacy and its units should be provided with normative acts that regulate the pharmaceutical business. For pharmacies that compound drugs it is obligatory to have State Pharmacopoeia.

In Ukraine, for example, for receiving the license pharmacy should prepare and have a passport of pharmacy (pharmacy point) issued in the established order. A general order of pharmacy (as legal person) opening is shown on scheme 6.6.

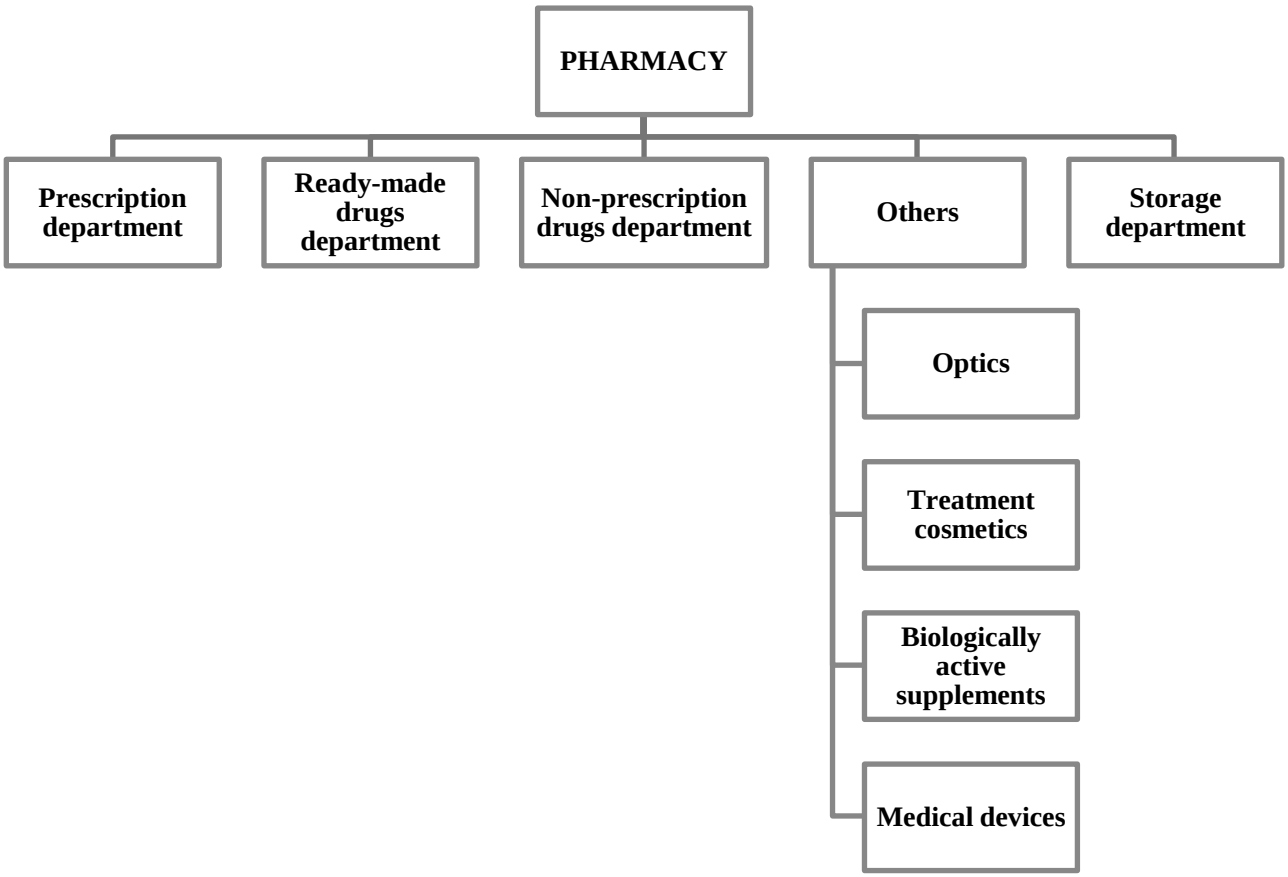


Scheme 6.6. General order of pharmacy opening

6.6. Organizational structure and staff of a pharmacy

The main task of the pharmacy activity is the proving of the population and health care establishments with medicines, hygiene items, nursing, disinfectants and other medical products.

Depending on the volume of work in pharmacies can be organized relevant departments (Scheme 6.7).



Scheme 6.7. Organizational structure of pharmacy

Prescription department receives prescriptions from the population; provide individual compounding of medicines and quality control, dispensing the medicines prescribed by doctors to the population and health care facilities by the requirement - invoices. In this department the injection solutions and eye drops that require special conditions (aseptic) have been compounded.

Department of ready-made drugs supply prescribed medicines of industrial origin (manufacturing) to the population according to the prescriptions.

Non - prescription department carries out the dispensing of non-prescription medicines, household sanitation and hygiene items, nursing, medical herbs and dressings.

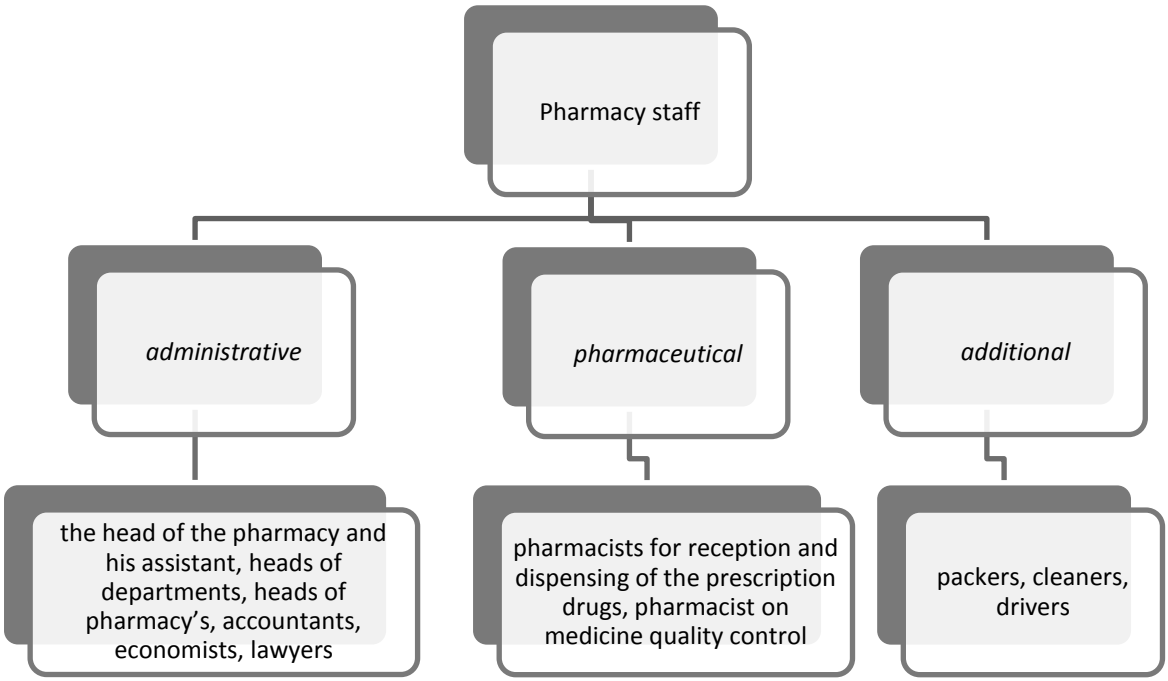
Storage department determine the need for medicines, receive drugs and medical devices from the pharmacy bases, ensure their proper storage and supply of other and departments, subdivisions (pharmacy points) and health care facilities and more. Production and accounting of all concentrates, intermediates and quality of their control have place also in the department.

In different countries other than pharmacies are also their structural subdivisions, for example, pharmacy points in Ukraine.

Pharmacy points as the structural subdivisions dispense ready-made drugs according to the prescriptions and without them. Pharmacy points should be located in separate apartments in hospitals. Area of pharmacy point can't be less than 18m^2. The room of pharmacy point have to be equipped with shelves, cabinets, fridge, safe or metal cabinet for storage of drugs, a place for sanitizing of hands, separate cabinets for storing of personal and special clothing, closet for storing of household equipment.

Staff (personnel) of a pharmacy. Quantity of pharmacy employers depends on the following factors: the type of productive activity, the volume of work, availability and the quantity of structural subdivisions (pharmacy points).

Staff of a pharmacy is divided into: administrative (management), pharmaceutical (production) and additional (Scheme 6.8).



Scheme 6.8. Staff (personnel) of a pharmacy

To *administrative staff* the head of the pharmacy and his assistant, heads of departments, heads of pharmacy's, accountants, economists, lawyers are included. As head of the pharmacy and its deputy can occupy only specialists with higher pharmaceutical education.

The *pharmaceutical staff* is divided into:

Pharmacists (for reception and dispensing prescription drugs, pharmacist-informant, pharmacist - analyst, a pharmacist of pharmacy point).

Additional staff – includes packers, cleaners, drivers and so on.

Staff of the pharmacies must meet united qualification requirements, continually improve their professional skills, ensure own systematic medical examination, have special clothes and shoes.

As usually, the rights and duties of pharmacy personnel are regulated by job descriptions (for each employee). In the pharmacy the following instructions are completed for all employees by staffing that can accommodate all activities and eliminate duplication. In drawing up job descriptions should be specify the interchangeability of employees in the event of the absence of person.

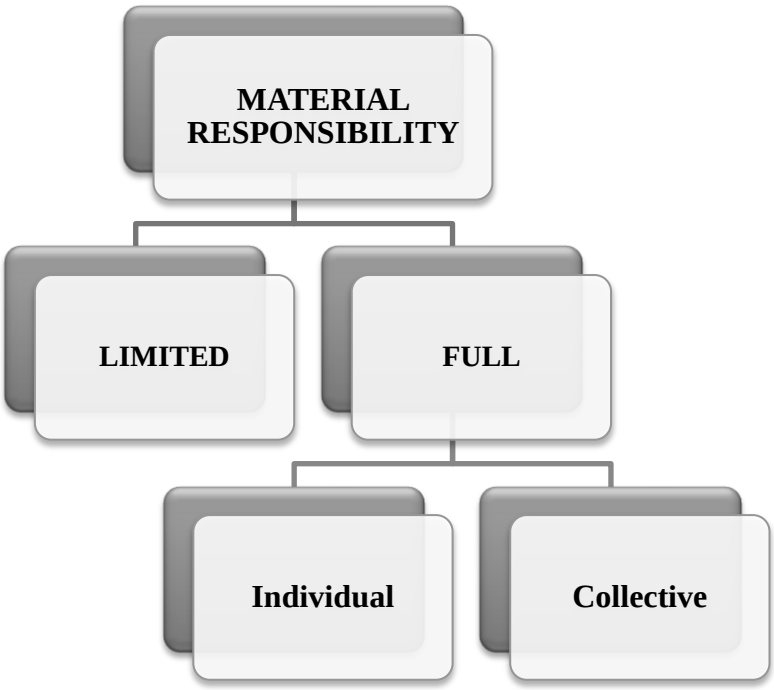
Material liability - a legal responsibility for losses caused to the property.

In addition, instructions appear: basic and additional duties, rights, regulations he has guided, responsibility.

To ensure the preservation of property owned by pharmaceutical companies the contract on full material liability (responsibility) with employees who directly related to the storage, processing, selling (dispensing), transport or use in the production values is signed.

The main purpose of material responsibility is to ensure safety of inventory by employee or group of employees and compensation by them losses that were caused by the pharmacy negligence or intentionally.

Types of material responsibility in a pharmacy are shown in Scheme 6.9.



Scheme 6.9. Types of material responsibility

Usually administration of pharmacy signs written contracts of full individual responsibility with employees occupying the following positions:

• cashiers who has responsibility for preserving cash and other securities;

• head of departments, if it is not possible to enter the collective (team) liability;

• pharmacists - heads of pharmacy points.

Administration decision on establishing of collective (team) liability (responsibility) issued by order of a head of the pharmacy and have to be announced at the general meeting.

It has a sense to establish a collective liability if the accounting and storage of inventories are separate in every department.

The employees have limited liability if the amount of caused damage does not exceed the average monthly earnings, damage or destruction of the goods was due to negligence.

The employees have full liability if the property and other valuables were obtained on report or other document, or when the damage caused in criminal proceedings, alcohol intoxication, in the case of willful destruction of materials or another from the performance of job duties time.

References

1. Directive 2001/83/EC of the European parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use

http://ec.europa.eu/health/files/eudralex/vol-1/dir_2001_83_cons2009/2001_83_cons2009_en.pdf

2. Організація фармацевтичного забезпечення населення: Навч. посіб. для студ. вищ. навч. закл./ А.С. Немченко, А.А. Котвіцька, Г.Л. Панфілова та ін., за ред. А.С. Немченко. – Х.: Авіста-ВЛТ, 2007.

Review questions

1. What are the basic principles of development and placing of pharmacy network?
2. Call the basic tasks and functions of pharmacy (farm. firms).
3. How can you classify the pharmacies?
4. Describe an organizational structure of pharmacy (farm. firms), its equipment.
5. What tasks and functions of departments do you know?
6. Explain the essence of pharmaceutical care as a pharmaceutical, medical and social category.
7. Describe the value of pharmaceutical care as a pharmaceutical, medical and social category.

Check Your Understanding

1. A pharmacy carries out preparation of intrachemist`s manufacture of concentrates, ready-to-use drugs and others. What license must pharmacy have?

A For the retail and wholesale sales of medicines

B For the retail sales of medicines

C For the wholesale sales of medicines

D For the retail sales and compounding (manufacture)

E For compounding and wholesale sales of medicines

2. A pharmacy got a license for the retail sales of medicines. Indicate the operation, which is **NOT** allowed by the license:

A Sales of the ready-made drugs to the ambulatory patients

B Sales of the ready-made drugs to the stationary patients

C Sales of commodities to establishments with future commercial use

D Free of charge sales to the chronic patients

E Sales of extemporeus drugs

3. The effective pharmaceutical care is impossible without the following terms (mark a correct answer):

A Presence of objective information about medications at the pharmaceutical market

B Collection of medicinal anamnesis sick

C High solvency of population

D Observances of norms of professional pharmaceutical ethics

C Competition of firms-producers at the pharmaceutical market

4. The basic elements of pharmaceutical care include (mark a correct answer):

A Possibility of replacement by preparation-analogue within the framework of non-prescription medicine

B Elucidation of questions of co-operation of medications with the food products and additions

C Diagnostics according to the complaints of patient and results of laboratory and clinical analyses

D Adjustment of doses of non-prescription preparation according to the age

E Recommendation to visit a doctor of definite specialization.

5. The pharmaceutical company plans to open pharmacy. List the key documents required to obtain permit for the retail sale of drugs.

Chapter 7. THE CONCEPTION OF SELF-MEDICATION AND OTC DRUGS

7.1. Self Medication as a major form of self care

Self-care is what people do for themeselves to establish and maintain health, prevent and deal with illness.

It is a broad concept encompassing:

• Hygiene (general and personal);

• Nutrition (type and quality of food eaten);

• Lifestyle (sporting activities, leisure etc.);

• Environmental factors (living conditions, social habits, etc.);

• Socioeconomic factors (income level, cultural beliefs, etc.);

• Self-medication.

Self medication can be defined as the use of medicine without any professional supervision. It aims to find the reason of self medication and make public aware about its effects and side effects. People use it for the treatment of any disease symptoms or minor ailments by their self initiative. The percentage of self medication might be changes with locality and region.

Self-medication is the selection and use of medicines by individuals to treat self-recognised illnesses or symptoms.

Self medication is a major form of self-care. It involves the use of medicinal products by the consumer to treat self recognized disorder, symptoms, recurrent disease or minor health problems. It is independent of age for both males and females. Medicines for self medication are often called Over the Counter (OTC) drug, which are available without a Doctors prescription through pharmacies, mostly in the less developed countries. The most commonly available OTC medications are pain killers, cough and cold remedies, anti-allergy medicines, vitamins and energy tonics. Although these medications are considered risk free and useful for the treatment of common health problems, their excessive use can also lead to serious side effects and unfavorable reactions.

Recent development of the pharmaceutical companies contribute to a wide spread availability of OTC Medicine. A major problem of self medication with antimicrobials is the emergence of human pathogens resistance world wide particularly in developing countries, where antibiotics are often available without a prescription. Its irrational use increases the risk of adverse events, bacterial infection, hypersensitivity, drug withdrawal symptom and of masking disease which can delay correct diagnosis.

Self medication is a common practice and internationally has been reported as being on rise and can produce a good result and be a convenient practice for patient. Self medication particularly with antibiotics has been widely reported leading the WHO to call attention to the dangers of self medication as a cause of antibiotic resistance.

Modern consumers (patients) wish to take a greater role in the maintenance of their own health and are often competent to manage (uncomplicated) chronic and recurrent illnesses (not merely short-term symptoms) after proper medical diagnosis and with only occasional professional advice. They are understandably unwilling to submit to the inconvenience of visiting a doctor for what they rightly feel they can manage for themselves, given adequate information. Self medication is very common and a number of reasons could be enumerated for it.

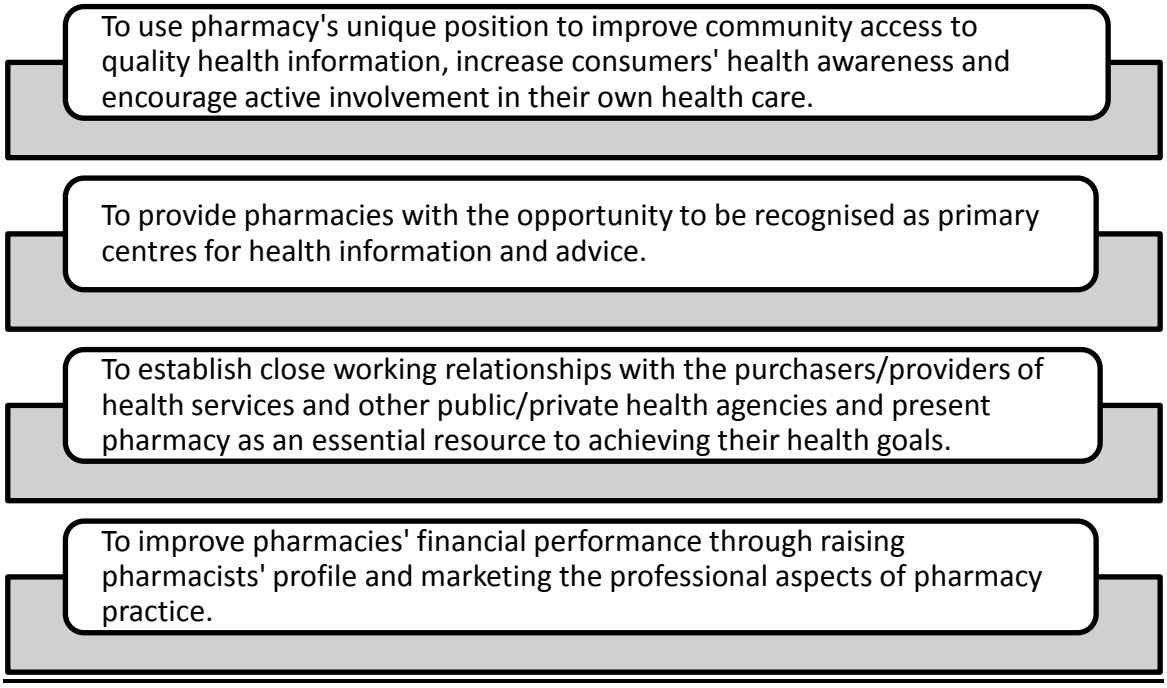
The pharmacist is a primary health care practitioner

WHO is readily accessible and provides people with:

- information and services on staying well and avoiding health problems;
- oral and written information on health problems;
- disease treatment and assistance in solving health problems; and

support during the course of their treatment.

Pharmacy Self Care Goals is represented at scheme 8.1.



Scheme 7.1. Pharmacy Self Care Goals

7.2. Duties of pharmacist in self medication

Duties of the pharmacist have been changing over the past two decades with self treatment increasing worldwide. He can play a key role in giving advice to consumers on the proper and safe use of medicinal products intended for self medication. It is important, therefore to take this role into account both in their training and in practice. In other words pharmacists play a valuable role in identifying, solving, and preventing drug-related problems (DRPs) for the purpose of achieving optimal patient outcomes and quality of life. Ambulatory based pharmacists have the opportunity and responsibility to foster safe, appropriate, effective, and economical use of all medications, especially those therapies patients are self-selecting. Pharmacists are uniquely trained to assist patients in the selection of appropriate drug therapy and the circumstances under which a physician should be consulted before patients embark upon independent self-care. Unlike above role, Pharmacists have following function.

As a communicator:

• the pharmacist should initiate dialogue with the patient (and the patient’s physician, when necessary) to obtain a sufficiently detailed medication history;

• in order to address the condition of the patient appropriately the pharmacist must ask the patient key questions and pass on relevant information to him or her (e.g. how to take the medicines and how to deal with safety issues);

• the pharmacist must be prepared and adequately equipped to perform a proper screening for specific conditions and diseases, without interfering with the prescriber's authority;

• the pharmacist must provide objective information about medicines;

• the pharmacist must be able to use and interpret additional sources of information to satisfy the needs of the patient;

• the pharmacist should be able to help the patient undertake appropriate and responsible self-medication or, when necessary, refer the patient for medical advice;

• the pharmacist must ensure confidentiality concerning details of the patient's condition.

As a quality drug supplier:

• the pharmacist must ensure that the products he/she purchases are from reputable sources and of good quality;

• the pharmacist must ensure the proper storage of these products.

As a trainer and supervisor:

To ensure up-to-date quality service, the pharmacist must be encouraged to participate in continuing professional development activities such as continuing education.

The pharmacist is often assisted by non-pharmacist staff and must ensure that the services rendered by these auxiliaries correspond to established standards of practice.

To achieve this the pharmacist must develop:

• protocols for referral to the pharmacist;

• protocols for community health workers involved with the handling and distribution of medicines.

The pharmacist must also promote the training and supervise the work of non-pharmacist staff.

As a collaborator:

It is imperative that pharmacists develop quality collaborative relationships with:

- Other health care professionals;
- National professional associations;
- The pharmaceutical industry;
- Governments (local/national);
- Patients and general public.

As a health promoter:

As a member of the health-care team, the pharmacist must participate in health screening to identify health problems and those at risk in the community, participate in health promotion campaigns to raise awareness of health issues and disease prevention, provide advice to individuals to help them make informed health choices.

Responsible self-medication

This is the practice whereby individuals treat their ailments and conditions with medicines which are approved and available without prescription, and which are safe and effective when used as directed.

Responsible self-medication requires that:

- Medicines used are of proven safety, quality and efficacy.
- Medicines used are those indicated for conditions that are self-recognisable and for some chronic or recurrent conditions (following initial medical diagnosis). In all cases, these medicines should be specifically designed for the purpose, and will require appropriate dose and dosage forms.
- The increasing importance of self-care and self-medication. The role of the pharmacist has been changing over the past two decades. The pharmacist is no longer just a supplier of medicines and a concocter of medicinal products, but also a team member involved in the provision of health care whether in the hospital, the

community pharmacy, the laboratory, the industry or in academic institutions. Pharmaceutical care is growing in importance with the challenges of self-care. For pharmacists, their greater involvement in self-care means greater responsibility towards their customers and an increased need for accountability. The increase in self-care is due to a number of factors. These factors include: socioeconomic factors; lifestyle; ready access to drugs; the increased potential to manage certain illnesses through self-care; public health and environmental factors; greater availability of medicinal products; and demographic and epidemiological factors.

7.3. The Responsibilities of Pharmacists

Pharmacists are increasingly recognized as key players in health care delivery. Providing information about minor illness treatment and the selection of OTC products are now recognized as critical duties for pharmacists around the world.

Pharmacy organizations have established practice guidelines for pharmacists when dealing with self-medication. The Fédération Internationale Pharmaceutique (FIP) states several principles for pharmacists when offering professional care to patients in the self-care area. The statements of principle are as follows:

Pharmacists have a professional responsibility to provide sound, unbiased advice and to ensure that self-medication is resorted to only when it is safe and appropriate to do so.

The pharmacist is ideally qualified and placed to advise on the need to consult a prescriber and that advice, because it will be based on expert knowledge, is bound to be better and safer than advice given by a friend or member of that person’s family.

Pharmacists have the necessary knowledge to advice on safe storage of medicines in the home and on safe disposal of medicines once a course of treatment has been completed or, in the case of a medicine, which is obtained for occasional use, when the expiry date has been reached.

Pharmacists can also advise that medicines prescribed for one individual or purchased for the treatment of a specific medical condition should not be used by another person without professional advice first being sought.

Pharmacists have a responsibility to report to the person's doctor, the manufacturer, and the regulatory authorities for medicines, any relevant information about an adverse reaction encountered by an individual, who may be associated with a medicine purchased without prescription.

The pharmacist shall locate non-prescription drugs in the area of the pharmacy consistent with the appropriate drug schedule classification which reflects the level of risk of the drug.

The pharmacist shall be available, accessible and approachable to consult with the patient who is seeking to self-medicate with a non-prescription drug. The pharmacist shall interact with the patient to receive and provide information needed when that patient is seeking to self-medicate with a non-prescription drug.

The pharmacist shall respect the patient's right to confidentiality by endeavouring to ensure that pharmacist/patient communication takes place in an area where the discussion cannot be overheard by others.

Where continuity of care is an important factor in achieving an optimal therapeutic outcome, the pharmacist shall document the service provided.

The pharmacist, and/or the pharmacy manager, shall assemble the human, material and financial resources needed to promote the rational use of non-prescription drugs.

7.4. Advantages & disadvantages of self medication

Advantages:

Expected health benefit from self medication depends on perceived effectiveness of self medication. In a world of scarce government and in many countries scarce individual resources, responsible self medication should be a

cornerstone of healthcare provision and health policy. Responsible self medication can:

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

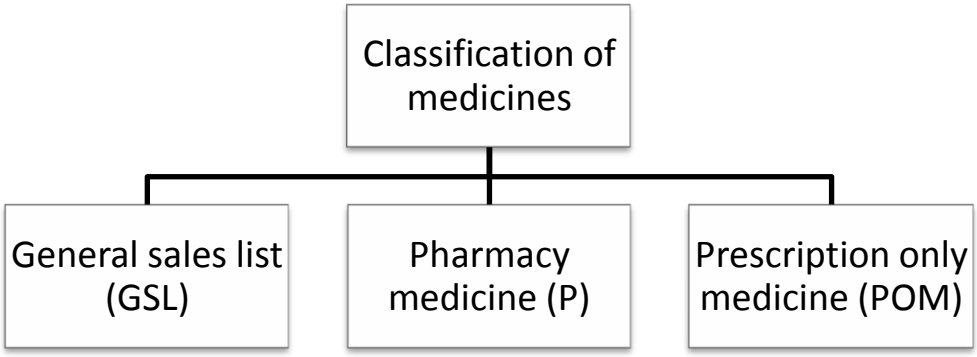
These benefits translate These benefits translate into patient and consumer wellness and productivity, economic gain for employers, and cost savings to healthcare budgets through reduced medicine budget cost and reduced physician visits. These conditions aim at ensuring the safety of taking self medicated drugs. They include the following: the drugs used are those indicated for conditions that are self recognizable; the user should know how to take or use the drugs; the effects and possible side effects of the drugs as well as ways of monitoring these side effects are well communicated to the user; possible interactions with other drugs is known by the user; duration of the course of the drugs is known by the user and, when the user must seek professional intervention.

Disadvantages:

Modern medicine have become absorbed rapidly in to the local custom through out the world, their ubiquitous distribution, powerful marketing and poor control mean that they are used and misused for a wide range of applications[40]. Misuse is defined as using an OTC product for a legitimate medical reason but in higher doses or for a longer period than recommended, e.g. taking more of a painkiller than recommended to treat a headache. Reports have proven that Paracetamol, an antipyretic and analgesic in large doses can cause liver failure. Paracetamol toxicity is, by far, the most common cause of acute liver failure in both the United States and the United Kingdom. It is also not a very greatly advertised fact that coffee consumed with Paracetamol or too much of alcohol consumption in association with the drug usage, can cause unprecedented liver failure rates.

7.5. OTC Pharmaceutical Products

According to the sales three legal categories of medicines have been defined. These are shown at scheme 7.1.



Scheme 7.1. Classification of medicines according to the sales

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 ís 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.

Every body 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.)

One more classification that is certainly used at chemists devides them for two groups: prescription and non-prescription drugs (table 7.1).

Table 7.1

CLASSIFICATION OF DRUGS				
PRESCRIPTION		NON- PRESCRIPTION		
READY-MADE	EXTEMPOREOUS	READY-MADE	THINGS FOR MEDICAL CARE	PLANT DRUGS
Tablets, capsules, pills, inhalation products, gels, powders, ointment, suppositories, liquids such as syrups, solutions, suspensions, mixtures, drops, tinctures and decoctions ets.			thermometers, cups, hot-water bottles, bandages, cotton and gauze etc.	

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

manifactured at pharmaceutical factory. EXTEMPOREOUS - a drug which is making under the prescription.

Technologists usually use the classification according to the medicinal form (table 7.2).

Table 7.2

Classification of medicinal forms			
solid	soft	liquid	gas
tablets, capsules, pills, powders	gels, ointment	syrups, solutions, suspensions, drops, mixtures, tinctures and decoctions	inhalation products

Any medicinal product which is used in self medication to treat ailments, not requiring a doctor's prescription. The term OTC first appeared in USA, in 1951 Durham-Humphrey Amendments to the Federal Food, Drug, and Cosmetic Act provided the statutory basis for the two-tier drug classification system that currently exists in the United States.

Nowadays, most people have experience using OTC medicines. People often use OTC products to treat their minor illnesses, which usually are common health problems such as colds, headaches, heartburn, and sore feet.

An OTC medicine is a medicine that can be purchased without a prescription from a physician. When a prescription medicine has been used for a long time and is considered safe and effective, to have low potential for misuse/abuse, and will pose minimal problems with average consumer use, manufacturers can apply to have it deregulated to OTC status. If that status is granted, the medicine may then be sold without prescription.

Thus, OTC drugs are medicines that may be sold directly to a consumer without a prescription from a health care professional, as compared to prescription drugs, which may only be sold 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.

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 literally 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 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 from country to country. OTC drugs groups used nowadays are showed in table 7.3.

Table 7.3

OTC Drugs Groups used nowadays

Antacids and Acid Reducers
Antiemetics
Antidiarrheal Medicines
Antihistamines
Decongestants
Cough Medicines
Herbal Products and Supplements
Laxatives
Pain Relievers
Condoms and other contraceptive devices
Contact lenses solutions
Anti-hemorrhoids
Smoking cessation aides
Cosmetics,perfums and skin treating creams and lotions
Antiseptics,mouth washes…etc
Soap
Tooth pastes
Vitamins taken to improve overall health
Sleep aids
Fiber and dietary supplements….and many others….etc

OTC products are an important element of self-care. Due to greater availability of such products and increasing interest in self-care, use of OTCs is also increasing.

7.6. 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

g_Antiinfectives for systemic use

h_Antineoplastic & immunomodulating agents

i_ Musculo-sketal system

j_ Nervous system

k_ Antiparasitic products

l_ Respiratory system

m_Sensory organs

n- 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 – Aluninium compounds.

5th level - is the subgroup for the chemical substance. (international unpatented name of therapeutical active ingredient) and indicated again by two arabic number:

A02AB02 – Algeldratum;

A02AB04 – Carbaldratum.

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

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Review questions

1. Indicate basic economic and social pre-conditions of origin of conception of.
2. Describe organizational terms of introduction of responsible self-medication conception.
3. Call the basic elements of conception of responsible self-medication.
4. What are the duties and responsibilities of the pharmacist in the conception of responsible self-medication?
5. What are the advantages and disadvantages of self medication?
6. Give the characteristic of the OTC medicines. What are the basic requirements to OTC drugs?

Check Your Understanding

1. Important pre-conditions of origin of responsible self-treatment conception are (mark correct answer):

A Increase of morbidity of population in the separate regions

B Change in the age structure of population toward the «senescence»

C Increase of market capacity of original preparations

D Increasing of quality of life

E Rising in price of medical services

2. Terms of conducting of responsible self-treatment are (mark a correct answer):

A Sponsorship of definite categories of population (invalids, chronic patients) from the side of state

B High general qualification of greater part of population of the country

C Presence of the national Essential drugs list ratified by the order

D Developed sector of the imported preparations at the pharmaceutical market

E High level of development of information about the non-prescription preparations

3. Advertising of non-prescription drugs must not contain such information:

A Name of medicine

B Gives the impression, that medical consultation at specialist is non-obligatory

C Objective information, necessary for application of medicine

D Attentively to read the instruction

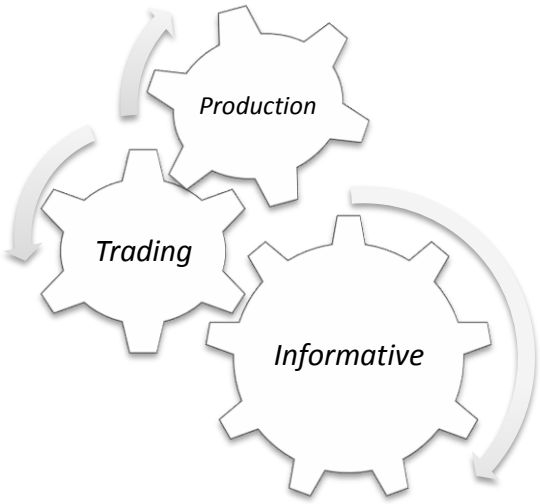
E Clear and exact information about correct and safe application of preparation

Chapter 8. THE ORGANIZATION OF WORK OF PRESCRIPTION DEPARTMENT IN PHARMACY. RULES OF EXCERPTION AND RECEPTION OF RECIPES

8.1. Organization of work of prescription department.

A prescription department is the department for reception of prescriptions and delivery of drugs. At this department medicines are made and sold according to the doctors 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 (Scheme 8.1.)



Scheme 8.1. The functions of the prescription department

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;
- makes the compounding, quality control, dispensing on prescription drugs and other medical assortment;
- carries out laboratory-filling operations (preparation of the concentrates, intermediate products and packaging of drugs).

Staff of the department. Head of the department and his assistant carry out management of the department. According to the staffing situation in the department there are assistants, pharmacists-technologists, and 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 the recipes:

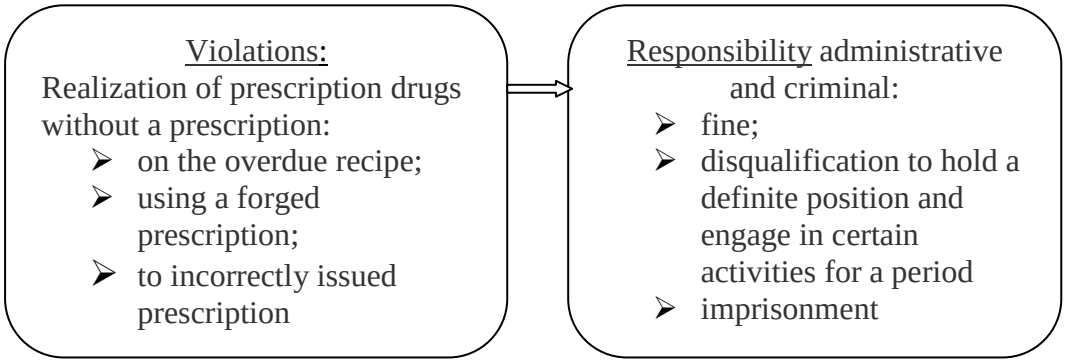
- Receiving prescriptions and requirements from the hospitals, checking the correctness of their design, compatibility of ingredients in the recipe, compliance of prescribed doses to the patient's age, determination of the cost of drugs;
- Accounting of received prescriptions and send them to compounding;
- 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 the 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).

Scheme 8.2. presents the responsibility for violations of pharmacist for the established rules of drug sales. 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.

The 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) in his/her work. Pharmacies are also used computer equipment, which allows quickly realize the medicines.



Scheme 8.2. Responsibility of a pharmacist for violating the established rules of drug sales

8.2. The organization of prescription medicines providing

The prescription is received and read by the pharmacist on the reception of recoups 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 *maximum dose* and *maximum daily dose* of the respective ingredients, and then upon their compatibility.

Maximum dose (md) means the maximum quantity of a substance contained in the amount of a medicinal product for internal use which it is recommended should be taken or administered at any one time.

Maximum daily dose (mdd) means the maximum quantity of a substance contained in the amount of a medicinal product which it is recommended should be taken or administered in any period of 24 hours.

After a pharmacist receives the prescription next steps must be done:

1. Stamp the clock number in duplicate on the blank and on the coupon, and call package, the coupon is then detached and handed to the waiting customer.

2. Write the label, using the prescription number and the clock number which also stamped on the label.

3. Record all facts in a book ruled for the purpose, as follows:

Clock number	Doctor	Patient	Article	Clerk
002483	Brown	Jones	R 4684	signature

4. The pharmacist then takes the prescription, label, etc., signs his name in the book, fills the prescription and stamps his name on the blank.

5. The pharmacist 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.

6. The pharmacist 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. 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.

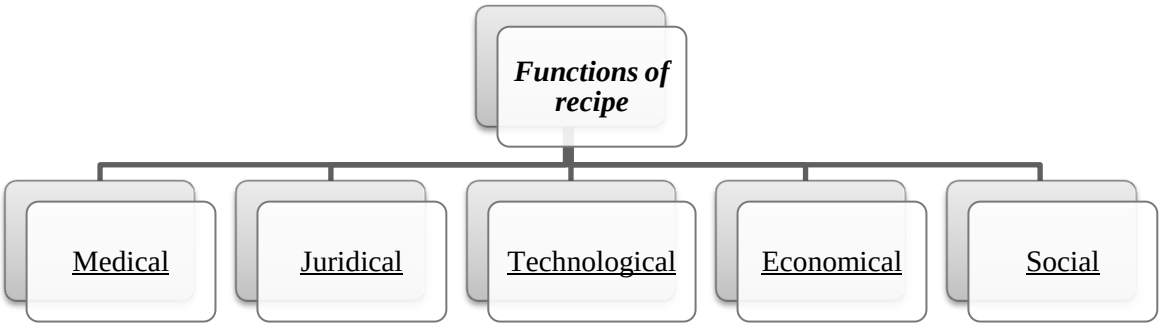
8.3. Organisation the work with prescription

8.3.1. 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. A prescription is a means of communication between the prescriber and the pharmacist.

Prescription: A physician's order for the preparation and administration of a drug or device for a patient. A prescription has several parts. They include the superscription or heading with the symbol "R" or "Rx", which stands for the word recipe (meaning, in Latin, to take); the inscription, which contains the names and quantities of the ingredients; the subscription or directions for compounding the drug; and the signature which is often preceded by the sign "s" standing for signa (Latin for mark), giving the directions to be marked on the container.

The order of excerption of recipes and remedies sales from pharmacies is regulated, by the basic orders of Ministry of health protection of Ukraine. Recipes have several functions (scheme 8.3)



Scheme 8.3. Functions of recipe

Medical – recipe is a document allowed medicines dispensing and using by patients in accordance to the doctor administrations about dosage and addition order, taking 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-economic status.

8.3.2. 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 administrated to a patient.

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

1. It is the language of science and is understood to a greater or less extends 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 affected by the use of the Latin technical terms.

The parts of prescription are:

1. **Inscriptio** – in this part of prescription name, address and phone number of health protection establishment is indicated.
2. **Datum** – date of excerption of recipe.
3. **Nomen aegroti** – the name of the patient. It should be placed at the top of the prescription by the prescriber and should be transferred to the lable by the pharmacist technologist.
4. **Nomen medici –** the name of the physician – the name of the doctor 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, 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 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.

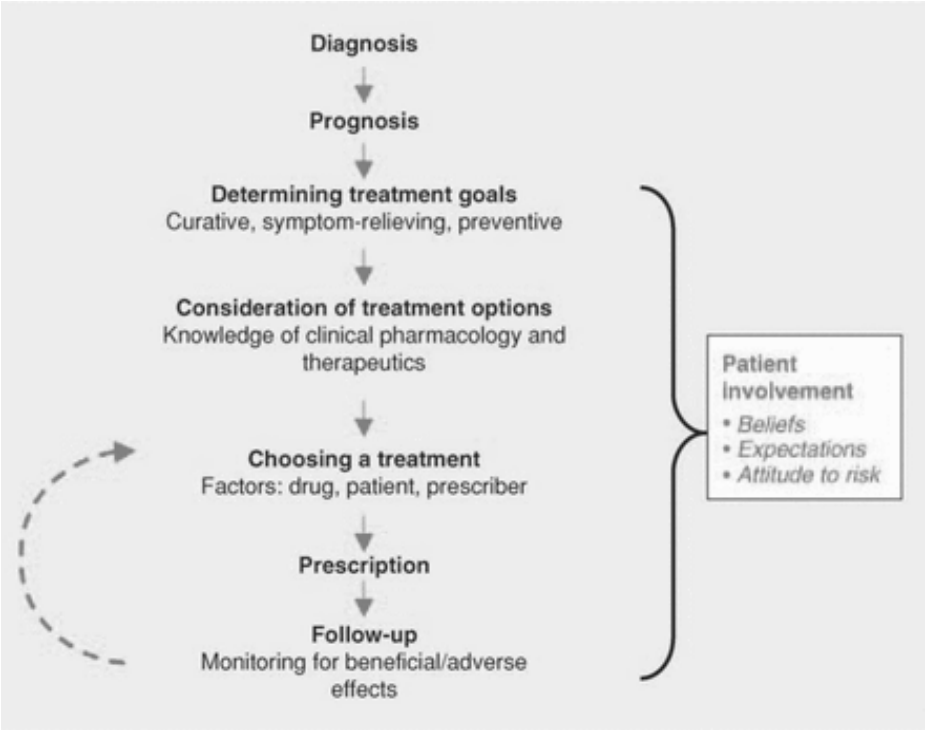
7. **Praescriptio or Subscriptio –** the subscription or the direction to the compounder – in the vest majority of prescription the subscription is contracted to a single letter or word, as M. or Misce, fiat etc. the physicians relies upon the skill of the pharmacist and generally gives no specific directions.

8. **Signatura –** the signa (mark) or the direction to the patient - it is usually abbreviated S. It should be written in full, explicitly and in native language for the patient.
9. **Subscriptio medici –** the signature and the stamp of the practitioner are the last part of the prescription.

8.3.3. Common rules of excerption of recipes

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).

Prescribing is a complex task that requires interpretation of evidence from clinical data in light of individual patient factors. Prevent different errors helps *rational prescribing.* Rational prescribing aims are to ensure that selection is not a simple formulaic linkage of drugs and doses to particular diagnoses, but involves individualizing prescriptions as far as possible, taking into account of the variables discussed above. We can review the process of rational prescribing as a whole. This process consists of six steps, each of which is discussed briefly (Scheme 8.4).



Scheme 8.4. Steps of rational prescribing

What at first seems just a simple consultation for only a few minutes, in fact requires a quite complex process of professional analysis. Patients make important contributions to rational prescribing decisions. Their beliefs and expectations affect the goals of therapy and help in judging the acceptable benefit-harm balance when selecting treatments. They will often play a key role in monitoring treatment, not least by providing early warning of adverse events. Thus, whenever possible, patients should be fully informed about their medicines.

The prescription, as an alternative to fulfilling the conditions specified above, may fulfill the following conditions unless the prescription is for a Controlled Drug.

It is forbidden to write recipes on medications which are not registered in the country. Nevertheless constantly in State Register of remedies is made alterations by the proper orders of MH that is conditioned in a number of reasons:

- by the appearing of new remedies on the pharmaceutical market 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.

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 in Ukraine versus Europe countries.

All recipes should be drawn up as follows:

1. Must be written in Latin;
2. Should be signed in ink with his own name by the appropriate practitioner giving it;
3. Should be written in ink or otherwise so as to be indelible, unless it is a health prescription which is not for a Controlled Drug;
4. Should contain the following particulars:
    - the address of the appropriate practitioner giving it;
    - the appropriate date;
    - such particulars as indicate whether the practitioner is a doctor, a dentist, a supplementary prescriber, a community practitioner nurse prescriber, a pharmacist independent prescriber, a nurse independent prescriber or an optometrist independent prescriber;
    - the name, address and the age, if under 12, of the patient.

- Should not be dispensed after the end of the period from the appropriate date, unless it is a repeatable prescription in which case it shall not be dispensed for the first time after the end of that period nor otherwise than in accordance with the directions contained in the repeatable prescription;
- In the case of a repeatable prescription that does not specify the number of times it may be dispensed, shall not be dispensed on more than two occasions unless it is a prescription for oral contraceptives in which case it may be dispensed six times before the end of the period of six months from the appropriate date.
- It is possible to use only acceptable Latin abbreviations for prescribing recipes (table 8.1).

Table 8.1

Traditional abbreviations in prescriptions

Abbreviations in Latin	**Full name**	**Translation**
aa	ana	equally, of each
ac., acid.	acidum	acid
amp.	ampulla	ampoule
aq.	aqua	water
aq. pur.	aqua purificata	purified water
but.	butyrum	butter
comp., cps., cp.	compositus (a, um)	compound
D.	Da, Detur, Dentur	to give out
D. S.	Da. Signa, Detur. Signetur	to give out, to administer
D. t. d.	Da (Dentur) tales doses	to give out such doses
dil.	dilutus	dissolved
div. in p. aeq.	divide in partes aequales	divide in equal parts
extr.	extractum	extract
f.	fiat(fiant)	let form
gtt.	gutta, guttae	drop
inf.	infusum	infusion
in ampull.	in ampullis	in ampoules
in tab.	in tabulettis	in tablets
lin.	linimentum	liniment
liq.	liquor	liquid, solution
M. pil.	massa pilularum	pill's masse
M.	Misce, Misceatur Misce, Misceatur	to mix
N.	numero	number
ol.	oleum	oil
pil.	pilula	pill
p. aeq.	partes aequeles	equal parts
pulv.	pulvis	powder
q. s.	quantum satis	of sufficient quantity
r., rad.	radix	root
Rp.	Recipe	to take
Rep.	Repete, Repetatur, Repete, Repetatur	repeat

Cont. table 8.1

rhiz.	rhizoma	rhizome
S.	Signa, Signetur	to administer
simpl.	simplex	simple
sir.	sirupus	syrup
sol.	solutio	solution
supp.	suppositorium	suppository
tab.	tabuletta	tablet
t-ra., tinct., tct	tinctura	tincture
unq.	unquentum	ointment
vitr.	vitrum	glass
ppt., praec.	praecipitatus	precipitated
past.	pasta	paste

The dose required must not be expressed in terms of the dosage form for single ingredient preparations e.g. "ATENOLOL 2 tablets" and should not be acceptable. It should be written as "ATENOLOL 100 mg".

Only the following abbreviations of way of administration (using) are acceptable in some countries of the world (table 8.2). 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. 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 8.2

Acceptable abbreviations

Acceptable abbreviations	Meaning	Acceptable abbreviations	Meaning
I.M.	for intramuscular	P.R.	for rectal
INHAL	for inhalation	P.V.	for vaginal
I.V.	for intravenous	S.C.	for subcutaneous
NEB	for nebulised	SUBLING	for sublingual
O.	for oral	TOP	for topical

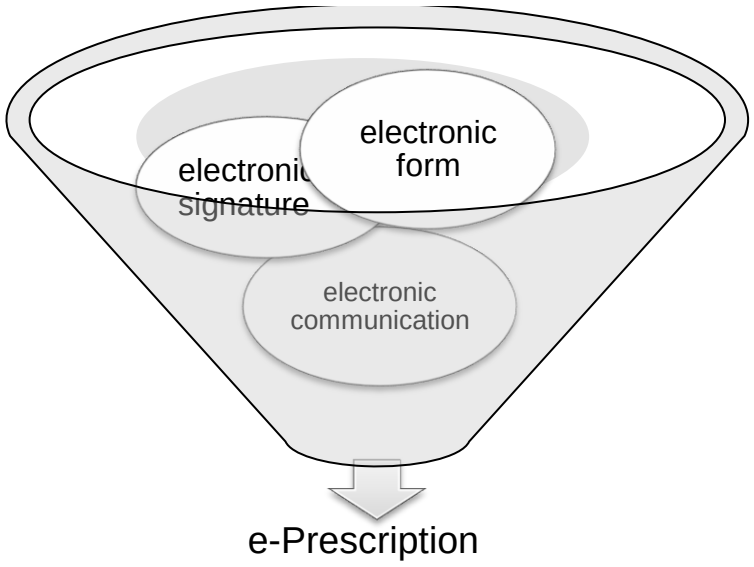
For certain medications, it may not be easy to define a maximum 24 hour dose (eg. for nebulised salbutamol, glyceryl trinitrate). In these situations the frequency of dosing must be prescribed but the time may be determined locally, in accordance with an agreed protocol or procedure. Premedication (before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

For controlled drugs, the prescriber's full signature is always obligatory. 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.

8.3.4. Electronic prescription as an important strategic policy to improve health care

The use of *electronic prescription (e-Prescription)* has been designated as an important strategic policy to improve health care. It is promoted in the USA, Canada and European Union. The aim of the e-Prescription is to have a cross-border electronic healthcare system in which will enable citizens to obtain e-Prescriptions anywhere in the world. The Scandinavian countries are leading Europe in deploying e-Prescription.

The e-Prescription is created in an electronic form. It is signed with an advanced electronic signature and is transferred to the person by whom it is dispensed as an electronic communication (Scheme 8.5).



Scheme 8.5. Composition of e-Prescription

Electronic prescriptions are the latest development in the prescription forms (Figure 8.1).

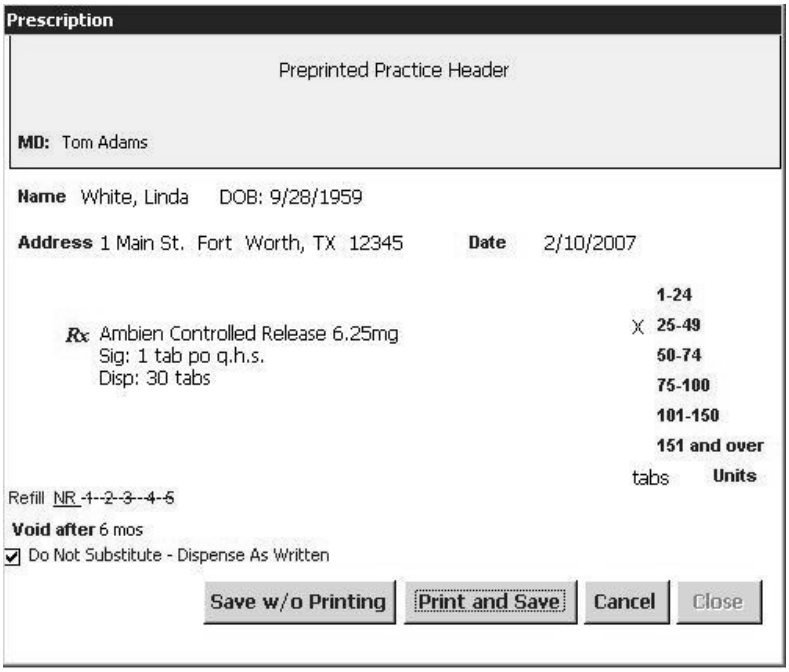
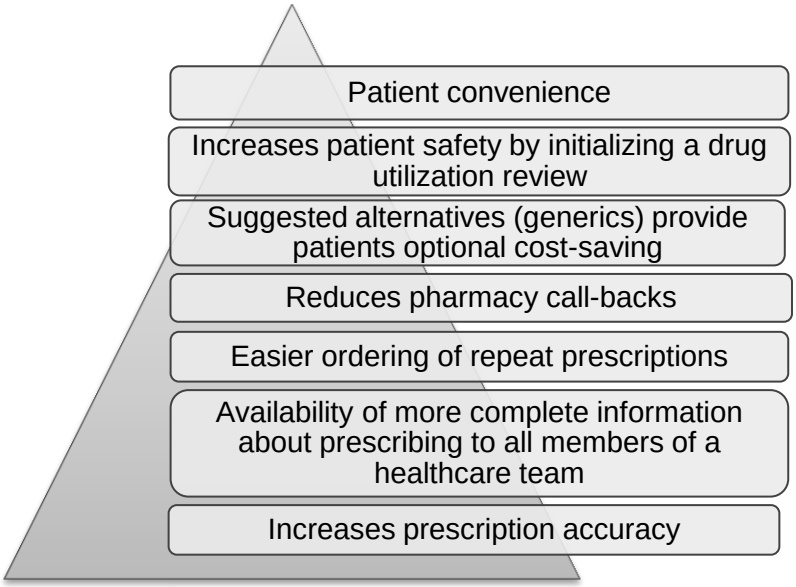


Figure 8.1. Electronic prescription

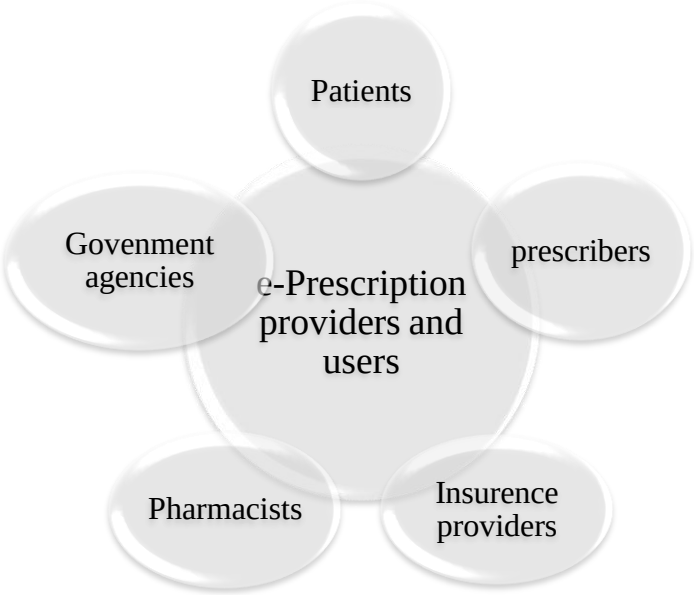
Electronic prescriptions will have the same legal force as a paper prescription and can eventually replace the latter completely, because of its benefits (Scheme 8.6).



Scheme 8.6. The benefits of electronic prescriptions

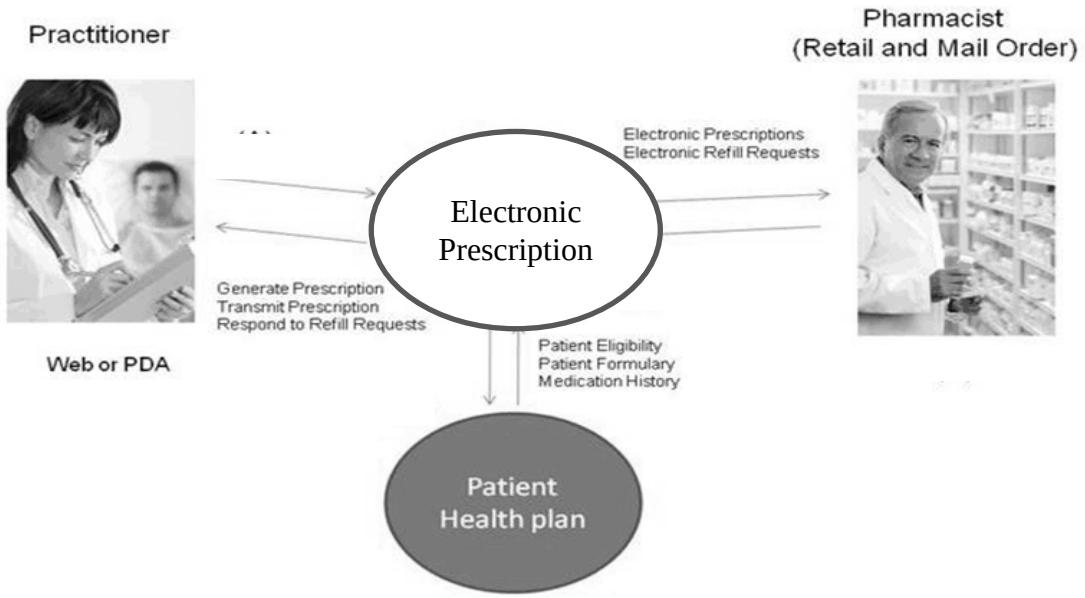
By transferring information about the prescriber's choice of medication for a patient electronically, a more holistic picture about the treatment regimen can be seen

by any member of the healthcare team, which will, in turn, improve the continuity of the patient's care (Scheme 8.7).



Scheme 8.7. Providers and users of e-Prescription

After writing the e-prescription, physicians can electronically fax to the pharmacy. Prescriptions can still be printed when necessary or if requested by the patient (Scheme 8.8).



Scheme 8.8. Mechanism of e-Prescribing

It helps clinicians increase patient safety, reduce pharmacy callbacks, and improve office efficiency. However, more importantly, there are consistently issues with the safety of the prescribing process as medication errors result in thousands of deaths annually.

8.3.5. Order of excerption of recipes in Ukraine

For excerption there are foreseen two types of forms of recipes are 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

Sodium phenobarbital

Barbamyle

Ephedrine hydrochloride etc.

❖ Poison medications, strong medicines (table 9.3)

❖ Others groups of medicines

Table 8.3

List of poisons and strong medicines

Poison medications	Strong medicines
Atropine sulfate	Dimedrole
Ketamine	Butorphanol
Tetracaine	Zopiclone
Tramadol	Clonidine
Trihexiphenidyle	Metandienone
Muscul relaxants: Atracurium, Vecuronium, Mivacurium, Pancuronium, Pipecuronium, Rocuronium, Suxamethonium, Tubocurarium, Cisatracurium	Nandrolon
	Promethazine

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: 1. – is not stored into pharmacy

2. – 1 year

3. -3 years, not counted current year

Form № 3

For excerption of narcotic and psychotropic medications and precursors 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 + leaders of health protection establishment signature.

A. Period of validity: 5 days.

B. Period of storage: 5 years, not counted current year.

Composition of medication, determination of technological form of medicine, address of doctor to the pharmacist about making and delivery of medications is written in 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 №1, is no more than 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 the Law of Ukraine "About languages in Ukraine") with

pointing of doses, frequency (periodicity) of application, and time of reception and duration of treatment. It is forbidden to be limited to the common pointing of type "External", "Internal" 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 grams.

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

a) Medicines which are subject to the 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 sales);
b) Medicines which are released free of charge and on favorable terms;
c) 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 favorable 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 precursors it is settled to write only to the doctors who 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 put 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.

Free of charge and privileged providing of drugs in Ukraine

The government in different countries have the program that will help people save on prescription drug bills, and it was created for uninsured and underinsured county residents nationwide. Through this discount the patients can help **save an average of about 20%** off the cost of prescription medications. However in certain cases individuals can save even more money. Some of the key factors that make this a great program include :

- **It is free. There are no costs.** There is absolutely no cost to consumers, the county taxpayers, or the local county government to participate in the savings program.

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 of Ukraine № 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 (table 8.4);

- A list of diseases for which outpatient drugs are provided free of charge (table 8.5).

Table 8.4.

Category of people who get medicines with benefits

Favorable realization (50% payment for the drugs)	Persons who have a rights to receive drugs free
❖ Disabled I-II group affected by the industrial injury, occupational or general disease	❖ Citizens, for whom it is provided by the Law "On Status of Veterans, Guarantees of their Social Protection"
❖ Disabled children groups I and II	❖ 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"
❖ 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	❖ Children under the age of 3 years
❖ Children aged from 3 to 6 years	❖ Those who affected by the Chernobyl disaster
❖ Persons awarded "Honorary donor Ukraine", "Honorary Donor of the USSR," according to the Law of Ukraine "On the donation of blood and blood components."	❖ 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
	❖ Disabled children under the age of 16 years

Table 8.5.

The diseases, for which drugs are released for free, include:

Cancer	Pituitary dwarfism
Hematological diseases	Condition after transplantation of organs and tissues
Diabetes	
Rheumatism	Unclosing spondylitis
Rheumatoid arthritis	Myasthenia gravis
Edema	Myopathy
Acute systemic lupus	Parkinson's disease
Asthma	Myocardial infarction (the first 6 m)
Systemic, chronic, serious skin diseases	AIDS
Syphilis	HIV infection
Leprosy	Postoperative hypothyroidism
Tuberculosis	Hyperparathyroidism
Addison's disease	Epilepsy
Hepatolenticular disease	Dysentery
Phenylketonuria	Congenital dysfunction of the adrenal cortex, etc.
Schizophrenia	

8.4. Control medicines in the international practice

Object-quantitative account (OQA) is documented accounting operational traffic of drugs that are subject to special control, which is to prevent their uncontrolled use. The essence of object-quantitative account is to register all transactions that change the number of drugs that are subject to this type of account in a special book (journal).

The list of medicines which are under the object-quantitative account in Ukraine is approved by Order № 360. It includes:

1. *Narcotic medicines* are substances of natural or synthetic origin, preparations, plants that are dangerous to human health in the event of abuse included in the list of narcotic drugs, psychotropic substances and precursors (approved by the Cabinet of Ministers № 770).

2. *Psychotropic* included in the list of substances of natural or synthetic origin, drugs, natural materials that are able to induce a state of dependence and produce depressive or stimulating effect on the central nervous system, or impair the perception, emotion, thought or behavior and pose a risk to health.

3. *Toxic and potent drugs* (by international non-proprietary names):

- Atropine and its salts (powder),
- Ketamine,
- Tetrakayin (powder),
- Tryheksyfenidyl,
- Atrakuriy,
- Vekuroniy,
- Pipekuroniy,
- Rokuroniy,
- Suksametoniy,
- Butorphanol (moradol etc.),
- Diphenhydramine (diphenhydramine) (solid form),
- Zopiklon,
- Klonidin (clonidine) (substance, liquid form),
- Methandienone,
- Nandrolone,
- Promethazine.

4. *Combinated medicines containing tramadol, ephedrine, pseudoephedrine and dekstropropoxyphen*.

Prescriptions for out-patients or patients on discharge which contain controlled substances 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 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

By the Law the pharmacist is not permitted to dispense prescriptions for controlled drugs, unless all the above information is detailed on the prescription.

destruction of any quantity of controlled drugs (however small) must be undertaken in the presence of a witness and the destruction recorded.

Medicines and substances that are subject to OQA have to be recorded in special journals (books) quantifying subject - which should be numbered, stamped pharmacy departments (departments, committees, etc.) and signed by their leaders.

The order of turnover of narcotic, psychotropic substances and precursors in pharmacies (activities of cultivation of plants included in the list, development, production, manufacture, storage, transportation, transfer, acquisition, implementation (leave), import into the territory of Ukraine, export from Ukraine and transit through territory of Ukraine, usage, destruction).

Analogues of narcotic drugs and psychotropic substances - prohibited for circulation in Ukraine synthetic or natural substances that are not included in the list of narcotic drugs, psychotropic substances and precursors, but the chemical structure and properties similar to those of narcotic drugs and psychotropic substances and reproduce their psychoactive effects.

Narcotic and psychotropic drugs that contain small quantities of narcotic substances, psychotropic substances and precursors from which these substances cannot be extracted readily available in quantities that allow you to abuse them, may be excluded from the application of certain control measures (or even dispensed without a prescription such as solpadein).

Legalization of drugs, psychotropic substances and precursors is carried out with the permission and under the control of public authorities subject to strict compliance with applicable law.

At the international level activities to combat illicit trafficking in narcotic drugs, psychotropic substances and precursors of the Commission on Narcotic Drugs of the Economic and Social Council of the United Nations (UN), the International Committee of the UN Drug Control, Interpol in accordance with international conventions: *Unified Convention "On narcotic drugs" (New York, 1961), as amended by Protocol "On corrections to the Unified Convention" (Geneva, 1972);*

United Nations Convention "On Psychotropic Substances" (Vienna, 1971); United Nations Convention "On fight against illegal circulation of narcotic drugs and psychotropic substances" (Vienna, 1988).

For example, in *India* the cultivation, production, manufacture, possession, sale, purchase, transportation, warehousing, consumption, inter-State movement, transshipment and import and export of narcotic drugs and psychotropic substances are prohibited, except for medical or scientific purposes and in accordance with the terms and conditions of any license, permit or authorization given by the Government and provides punishment for any contravention of the Order. An offender is liable for rigorous imprisonment, which may be extended to 10 years, and fine, which may extend to 100 000 rupees (1 600 $).

In the *United Arabian Emirates* the General Authority for Health Services Guide to the Management of Controlled Drugs in the Private Sector controlled drugs divide on Class A – Psychotropics and Class B – Controlled medicines. The punishment will be imprisonment.

All activities, related to drug trafficking, must be licensed. By the head order pharmacy should be a commission for receiving, keeping and destruction of narcotic drugs, psychotropic substances and precursors of at least 3 persons chaired by the head of the pharmacy or his deputy. The Commission shall carry out inspections of all narcotic drugs, psychotropic substances and precursors, which are received from suppliers, the compliance of their names, quality, quantity, weight, referred to in the accompanying documents suppliers (invoices, bills), check the integrity of the packaging, no shortage of (incomplete filling of vials, unclear labeling) expiration date, etc. Results of the checking are issued in the relevant Act.

In health care institutions narcotics, psychotropic substances and precursors should be kept in separate rooms, equipped according to the requirements of the object and premises intended for carrying out activities on narcotic drugs, psychotropic substances and precursors, approved by the Order of the Ministry of Internal Affairs from15.05. 2009 № 216.

The room, safes and metal cabinets, where are narcotics, psychotropic substances and precursors, after operations should be locked, sealed and put under protection. The right of access to this room have persons appointed by order of the head of the institution.

Narcotic drugs, psychotropic substances and precursors in powders, pills, which are part of dosage form, should be given by a pharmacist who controls the production process, in the place of storage in the presence of a pharmacist who receives and produces drugs. After this substanses should be immediately locked in the safe.

Obtained narcotic, psychotropic substances or precursor should be immediately used for the manufacture of dosage form, which immediately transferred to test the controller.

Documents on account of narcotic drugs, psychotropic substances and precursors should be stored under conditions that ensure complete safety, at least five years, excluding the current year.

According to current legislation pharmacies conducted quarterly inventory of controlled substances with the balance sheet inventory.

If there are any abnormalities in the balance sheet or non-factual and documentary evidence within 3 calendar days after detection of health care institution submitted information to the police.

Recipes for narcotic drugs, psychotropic substances and precursors that are written on special prescription forms F-3 must be kept in pharmacies 5 years, not including the current year.

At the end of the storage period recipes must be destroyed. Special commission burns them and feels the act of destruction.

8.5. Rules of pricing of extemporeus prescription

The price of the prescription drugs is the evaluation of the extemporal medicine considering the retail prices of substances included in its composition, as well as packaging and tariff for manufacturing.

Pharmacy's Tariff (Taxa Laborum) is evaluation of labor, material and other costs related to manufacturing of dosage form.

The price of the prescription must always be marked upon it. This is necessary in order to fix the sum in case of renewal.

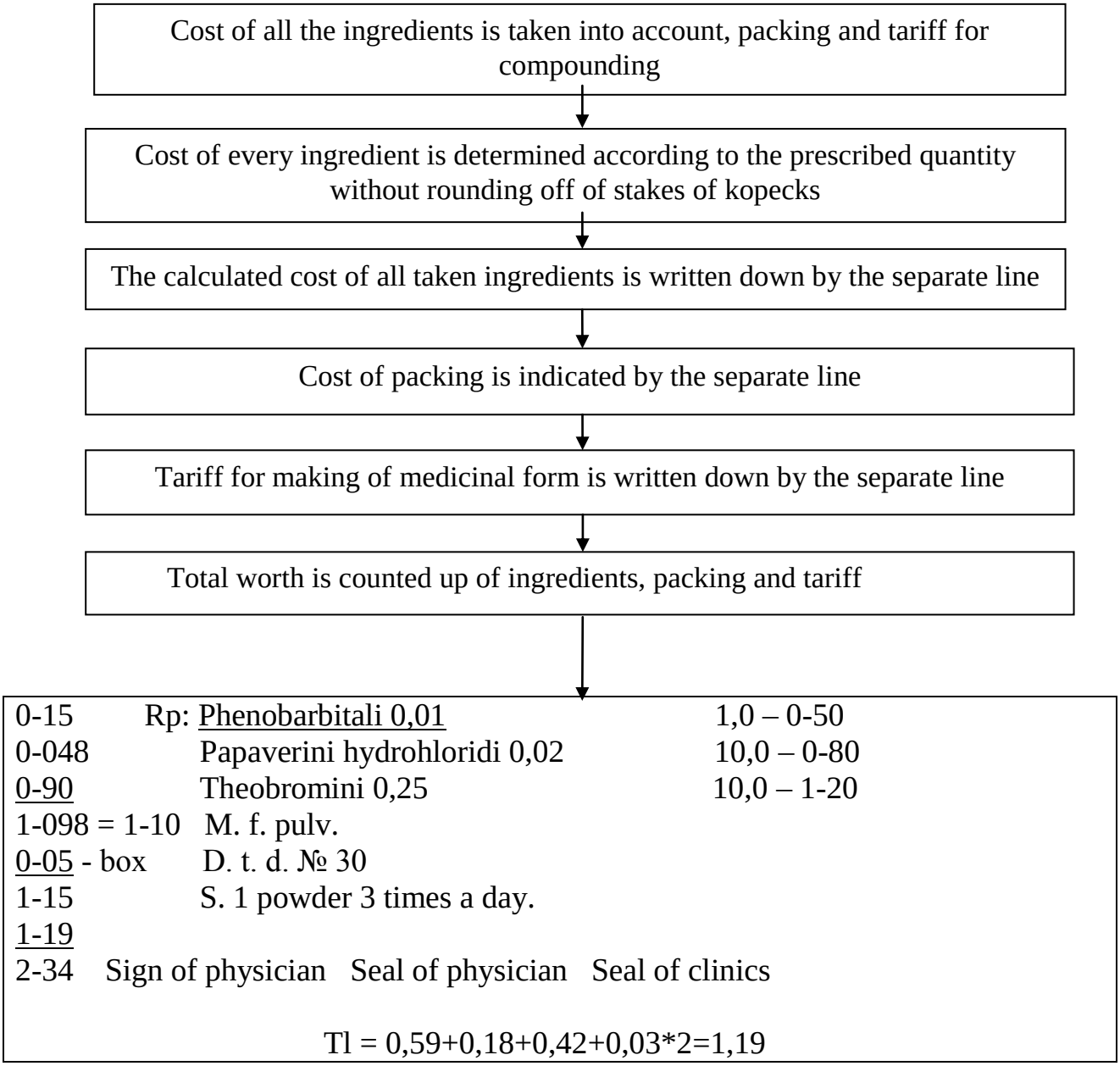
Historical aspects of Taxa laborum in the forming of retail prices for extemporaneous drugs. History of the apothecary tariffs starts from 1672 when first pharmacy was opened in Moscow. Since the tariffs for making medicines and health products packaging have been implemented the pharmacies get the possibility not only recover all the costs of the production process, but also earn a profit for the further development of logistics pharmacies.

The implementation of tariffs in pharmacies in Ukraine began in 1991 and was then introduced as the order that exists to this day, namely, "value of medicinal product prepared in a pharmacy is calculated by summing the cost of each ingredient that is consumed (including purified water, or for injection), the cost of packaging (cans, bottles, boxes, etc..) and the tarriff for manufacturing and packaging."

Tariffs at the pharmacy are accounted and reported in such documents:

- Tariffs for making extemporaneous drugs - the recipe, after the cost of ingredients and packaging, as well as register book;
- Tariffs for manufacturing dosage forms and packaging to stationary recipe - in - overhead requirements for each dosage form;
- Tariffs for intrachemists packing in the laboratory journal packing a box under the specification;
- Sum of tariffs received by drugstore for making extemporaneous drugs and packaging during the reporting period in the report of pharmacy per month.

There are common rules of pricing of extemporeus medicines (Scheme 8.10).



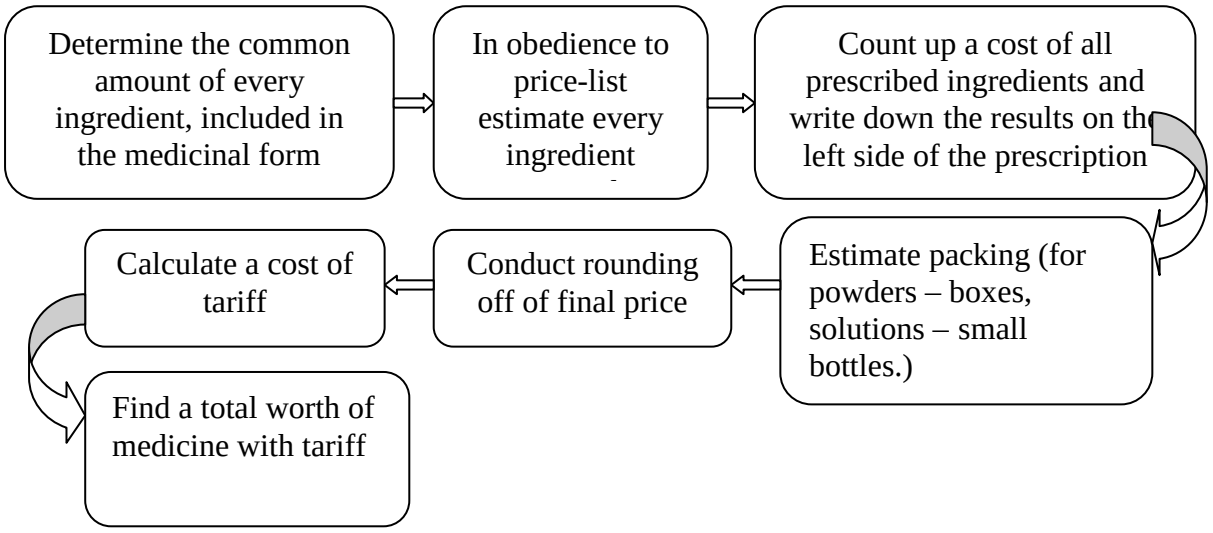
Scheme 8.10. Rules of pricing of extemporeus medicines

In some countries the price of the prescription includes:

The compounding fee + the cost of the package + twice the costs of the ingredients.

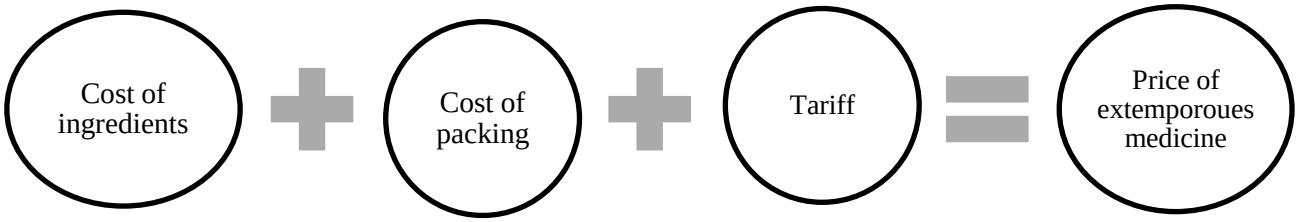
The cost of the package should also be known exactly and this with the cost of labels, paper etc., should next be added to the price.

Order of pricing of extemporeus drugs in Ukraine is presented on scheme 8.11*:*



Scheme 8.11. Order of pricing of extemporeus medicines in Ukraine

A cost of extemporeus medicinal form is presented on the sheme 9.12:



Scheme 8.12. Components of the price of extemporeus medicine

The procedure for determining the tariff should be taken fixed tariff for manufacturing dosage form, for powders and suppositories additionally assessed work on making each other dozen (1 to 10), over the first ten powders or suppositories.

Additional tariff is taken in the case when the specification includes one or more additional (more than two), each operation is evaluated adding the component (assessment for the introduction of an emulsifier, stabilizer as an additional component incorporated in the tariff for manufacturing dosage form and the calculation of the fare not included) and in case when the specification is poisonous, narcotic or equivalent material.

The actual time spent in compounding the prescription represent a definite cost and each prescription should carry its share of the general overhead expenses, such as a rent, light, heat etc., which make it possible to open the prescription department.

When the actual costs have been determined, the amount to be charged for profit may be given consideration. It may be a definite addition to the actual cost (from 10 to 20 percent).

A price is fixed which has been scientifically determined and in which there can be confidence should it be questioned. The proprietor is assured a reasonable profit.

References

1. Постанова КМУ №1303 від 17.08.1998 р. „Про впорядкування безоплатного та пільгового відпуску ЛЗ за рецептами лікарів у разі амбулаторного лікування окремих груп населення та за певними категоріями захворювань”
2. Постанова КМУ №770 „Про затвердження Переліку наркотичних засобів, психотропних речовин і прекурсорів” від 6.05.2000 р. (зі змінами)
3. Наказ МОЗ України №360 від 19.07.05 р. „Правила виписування рецептів та вимог-замовлень на ЛЗ і вироби медичного призначення”.
4. Визначення тарифів за індивідуальне виготовлення і фасування ЛЗ та ВМП аптеками (методичні рекомендації) / А.С. Немченко, К.Л. Косяченко, В.М. Чернуха та ін. – Київ, 2008. – 30 с.
5. Організація фармацевтичного забезпечення населення: Навч. посіб. для студ. вищ. навч. закл./ А.С. Немченко, А.А. Котвіцька, Г.Л. Панфілова та ін., за ред. А.С. Немченко. – Х.: Авіста-ВЛТ, 2007.
6. Немченко А.С. Фармацевтическое ценообразование.– Х.: Радар, 1999.– 290с.
7. National Association of Counties Prescription Drug Discount Card program http://www.needhelppayingbills.com/html/naco_prescription_drug_discoun.html
8. Definition of Prescription http://www.medterms.com/script/main/art.asp?articlekey=11896

Review questions

1. What are the functions prescription department?
2. Describe the main functions of recipe.
3. Who works in prescription department?

4. What forms of recipe do you know?
5. What is the structure of the recipe?
6. Who has the right to prescribe medicines?
7. Call the rules of prescribing medicines.
8. What category of people can get POM free of charge?

Check Your Understanding

1. From the groups of medicines, realized in the pharmacy, indicate that belong to the subject-quantitative account.

A Laxatives

B Psychotropics

C Antibiotics

D Steroid anti-inflammatory drugs

E Steroid hormones

2. What group of children in the case of ambulatory medical treatment has a right to get medicines free of charge?

A From 6 years

B From 3 to 6 years

C Up to 3 years

D From 16 years

E From 10 years

3. A pharmacist must quickly, out of turn to pass a prescription for making of medicinal preparation, if in the overhead part of prescription a doctor put:

A Exclamation mark

B "Cito" or "Statim"

C Two exclamation marks

D Three exclamation marks

E Term of vacation

4. Prescription entered the pharmacy designed with violation of requirements. Actions of pharmacist:

A To liquidate prescription by stamp “Prescription is invalid” and to return to the patient

B To give to the patient a copy of prescription

C To register a prescription in the proper journal and realize medicine to the patient

D To sell medicines

E To reveal to the manager of the pharmacy

5. A prescription on nose drops “Farmazoline” for the child of 2,8 years old has entered to the pharmacy`s department of the ready-made drugs. Indicate, for what cost medicines will be realized?

A On the overall cost

B With the payment 50 % of their costs

C Free of charge

D Some medicines free of charge

E The payment 70 % of their costs

Chapter 9. ORGANIZATION OF THE QUALITY CONTROLL SYSTEM OF PHARMACEUTICAL PRODUCTS

9.1. The organization of the State System of quality control of drugs in different countries

A main task of the National drug policy in accordance with WHO recommendations is providing of population with quality and effective medicines. Solving of the global problem of the providing of population with quality medicines in different countries placed on the State quality control system (hereinafter - System) with specific organs and structures. The quality control system - a series of organizational measures taken to ensure that the quality of medicines to their appointment from creation to usage and include implementation of these actions in accordance with Good Laboratory Practice, Good Clinical Practice, Good Manufacturing Practice and Good Distribution Practice. The primary purpose of a quality system is to ensure that adequate quality standards are maintained. The purpose of adopting a common standard for quality system requirements is to achieve consistency in inspection standards between GMP National Pharmaceutical Inspectorates and thus to facilitate mutual recognition of and mutual confidence between those Inspectorates.

Under the System understand the complex of administrative tools that requires from each subject of business supplying of population with pharmaceutical care, compliance with applicable regulations and statutory requirements.

PIC/I gives following definition - Quality system: The sum of all that is necessary to implement an organization's quality policy and meet quality objectives. It includes organization structure, responsibilities, procedures, systems, processes and resources. Typically these features will be addressed in different kinds of documents as the quality manual and documented procedures, modus operandi etc.

General Model of System is presented at scheme 9.1.

World experience of System's functioning shows that the most effective and economically rational way to ensure quality of Medicines is a complex of regular inspections and methods of analytical control in strict compliance by manufacturers with GMP standards. Therefore, efforts Systems in countries such as USA, Germany, United Kingdom focused mainly on the inspection of medicines, and focuses on

companies that are exporting countries. For example, FDA U.S. has about 7,000 inspectors and only about 300 employees of analytical laboratories. In countries with economies in transition Systems are under development and reorganization. They work in a legal and regulatory uncertainty, duplication and inconsistency of actions of structures and organs, deficit of financial and human resources, absence of state policy in sphere of medicines quality assuring etc. According to international experience and the requirements of WHO, National System must function to assure a quality of medicines at all stages of their life cycle.

Quality assurance of medicines at these stages should be ensured in accordance with licensing rules and standards of good practices (GCP → GLP → GMP → GDP → GPP). Additionally, input proper procurement practice ("Good Pharmaceutical Procurement Practice" - GPPR) and Good Storage Practices (GSP), which are recommended.

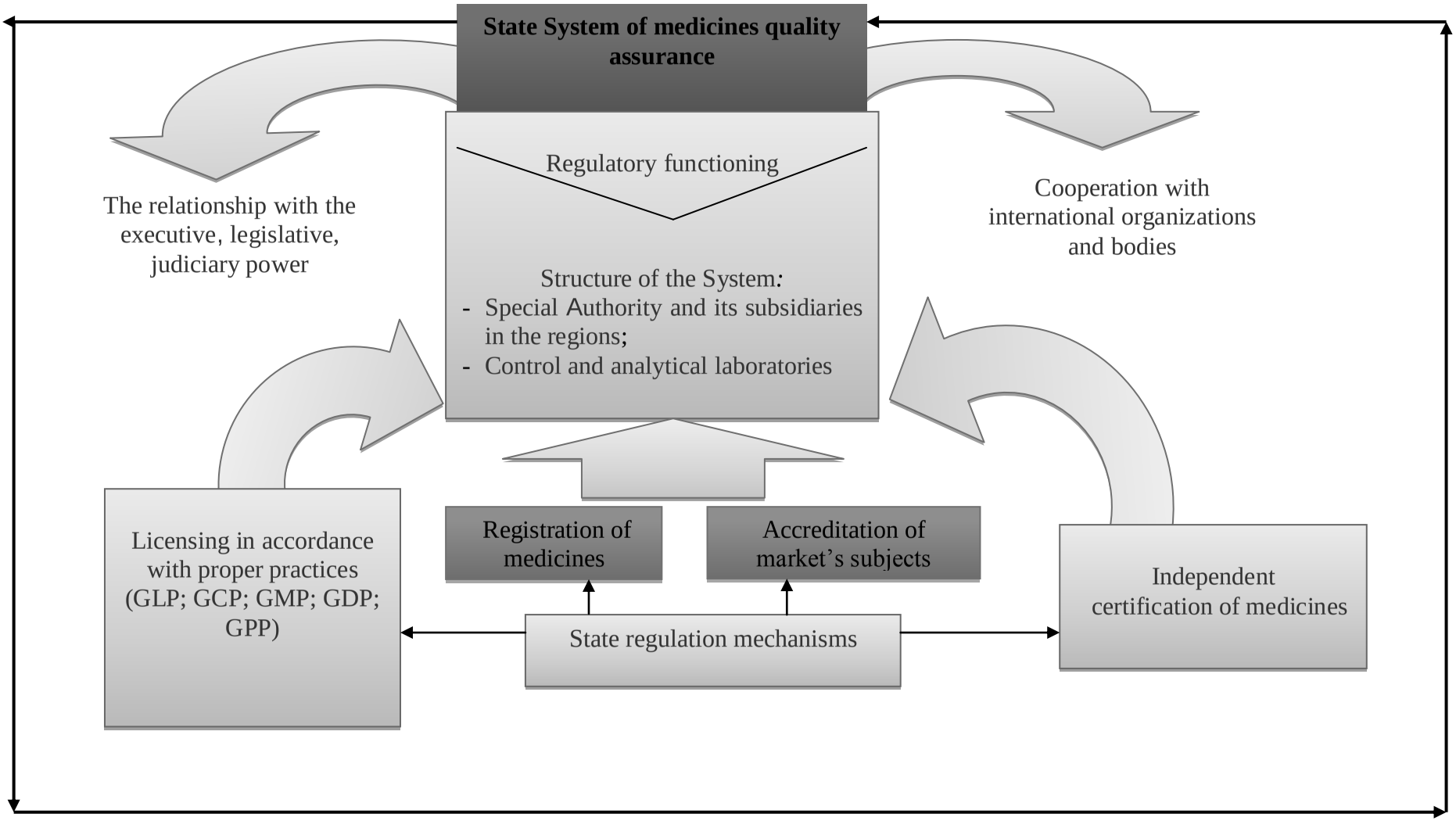
Central place in the structure of the National System has the authority empowered to exercise state control of medicines, which typically functioning in the structure of the Ministry of Health, in its direct subordination and has wide powers (scheme 9.2).

Pharmaceutical Inspectorate - the National body responsible for co-ordinating and carrying out of GMP inspections, including inspections of pharmaceutical manufacturers and/or wholesale distributors. If relevant, this could include making decisions concerning the issue or withdrawal of establishment licenses or authorizations for their activities, the issue or withdrawal of GMP certificates, providing advice and handling suspected quality defects. (http://www.picscheme.org/publication.php?id=17)

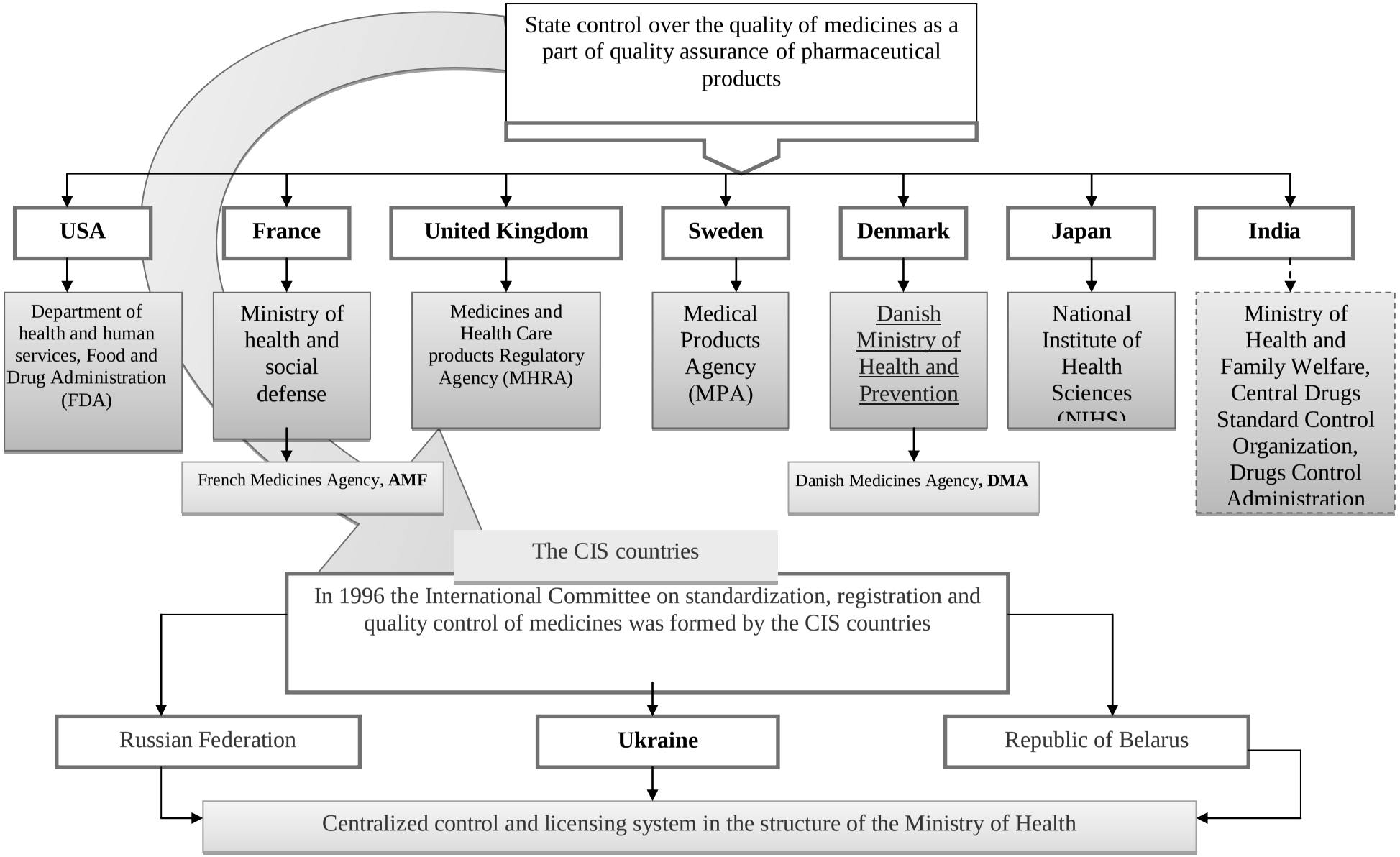
In accordance with WHO, special authority should have the following components:

• administrative unit with clearly defined rights and responsibilities of employees;
• Inspectorate Service
• Analytical laboratory with the necessary financial, personnel, regulatory, technical and information support.

The structure, membership and operation of the Pharmaceutical Inspectorate should be such as to enable it to meet the objectives of quality management and to ensure that impartiality is safeguarded.



Scheme 9.1. Model of State System of medicines quality



Scheme 9.2. The state structures of QA drugs in the Health care system structure

The personnel of the inspection service, including sub-contracted personnel and experts, should be free from any commercial, financial and other pressures which might affect their judgment and freedom to act. The Pharmaceutical Inspectorate should ensure that persons or organizations external to the inspection organization cannot influence the result of inspections. The system for obtaining fees should not improperly influence the inspection procedure. Rules for deontology, ethics, conflict of interest and improper influence should be clearly defined.

The relationship of the Pharmaceutical Inspectorate to other agencies and to other organizations within and outside the Inspectorate should be described where relevant.

The Pharmaceutical Inspectorate should have sufficient resources at all levels to enable it to meet its objectives effectively and efficiently. Senior management should ensure that all personnel are competent and qualified to carry out their assigned duties and that they receive appropriate training. Such training should be documented and its effectiveness assessed periodically.

The Pharmaceutical Inspectorate should conduct repeated inspections of manufacturers and/ or wholesale distributors and should issue inspection reports in accordance with National or European Community requirements as appropriate.

The Pharmaceutical Inspectorate should have the documented procedures and resources to enable inspection of manufacturing and wholesale distribution operations to be carried out in accordance with the official guidelines and National legislation and in accordance with a formal inspection plan. All instructions, standards or written procedures, worksheets, check lists and reference data relevant to the work of the Pharmaceutical Inspectorate should be maintained up-to-date and be readily available to staff.

When more than one inspector is involved in an inspection, a lead inspector should be appointed to co-ordinate inspection activities. The inspection report should normally be prepared by the lead inspector and should be agreed by all participating inspectors.

The Pharmaceutical Inspectorate should establish and maintain a system for the issue and withdrawal of licenses and GMP certificates, or for advising about the issue and withdrawal of licenses and GMP certificates, as appropriate.

The Pharmaceutical Inspectorate should establish and maintain a system for handling of reports of suspected quality defects in medicinal products as defined in a related Standard Operating Procedure or the related Community procedure.

The Pharmaceutical Inspectorate should establish and maintain a system for issuing Rapid Alert as defined in a related Standard Operating Procedure or the related Community procedure and an updated list of all performed recalls.

In different countries Pharmaceutical Inspectorate has its own specific. Thus, the US Food and Drug Administration is an agency of the United States Department of Health and Human Services, one of the United States federal executive departments. The FDA is responsible for protecting and promoting public health through the regulation and supervision of food safety, tobacco products, dietary supplements, prescription and over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED), veterinary products, and cosmetics. French Medicines Agency deals with import-export, certification, prohibition of medicines and so on. Medicines and Health Care products Regulatory Agency in the UK provides licensing of manufacturing, conducts a post-licensing monitoring and analytical testing of samples of medicines removed from realization, and is responsible for the information about medicines in the pharmaceutical market.

In Ukraine, as a special organ of the System is the State Administration of Ukraine on medicinal products (http://diklz.gov.ua).

To enhance the functioning the authority should work closely with the special authorities of other countries. There are Pharmaceutical Inspection Co-Operation Scheme (PIC/S) – http://www.picscheme.org/news.php, International Organization for standartization (ISO) – http://www.iso.org/iso/home.html, International Conference on Harmonization are held (ICN) etc.

The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S) are two international instruments between countries and pharmaceutical inspection authorities, which provide together an active and constructive co-operation in the field of GMP.

PIC/S' mission is "to lead the international development, implementation and maintenance of harmonised Good Manufacturing Practice (GMP) standards and quality systems of inspectorates in the field of medicinal products." This is to be achieved by developing and promoting harmonized GMP standards and guidance documents; training competent authorities, in particular inspectors; assessing (and reassessing) inspectorates; and facilitating the co-operation and networking for competent authorities and international organizations. There are currently 40 Participating Authorities in PIC/S (Convention and Scheme taken together) (table 9.1). Ukraine has become the 39th country to join this organization.

Table 9.1

List of PIC/S participating authorities (3 January 2012)
(in the alphabetical order of the country in which they are located)

Country	**PARTICIPATING AUTHORITY**	**ACRONYM**
Argentina	Instituto Nacional de Medicamentos *(National Institute of Drugs)*	INAME
Australia	Therapeutic Goods Administration	TGA
Austria	Austrian Agency for Health and Food Safety	AGES
Belgium	Agence Fédérale des Médicaments et des Produits de Santé *(Federal Agency for Medicines and Health Products)*	AFMPS
Canada	Health Products and Food Branch Inspectorate HPFBI	
Cyprus	Pharmaceutical Services CyPHS	
Czech Republic	Státní Ústav pro Kontrolu Léciv *(State Institute for Drug Control)*	SÚKL
	Ústav pro Státní Kontrolu Veterinárních Biopreparátu a Léciv *(Czech Institute for State Control of Veterinary Biologicals and Medicines)*	ISCVBM
Denmark	Danish Medicines Agency	DMA
Estonia	State Agency of Medicines	SAM
Finland	Finnish Medicines Agency	FIMEA
France	Agence Française de Sécurité Sanitaire des Produits de Santé *(French Health Products Safety Agency)*	AFSSAPS
	Agence Nationale du Médicament Vétérinaire *(French Agency for Veterinary Medicinal Products)*	ANMV

Cont. table 9.1.

Germany	Bundesministerium für Gesundheit *(Federal Ministry of Health)*	BMG
	Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten *(Central Authority of the Laender for Health Protection regarding Medicinal Products and Medical Devices)*	ZLG
Greece	*National Organization for Medicines*	EOF
Hungary	National Institute of Pharmacy	NIP
Iceland	The Icelandic Medicines Agency	IMA
Ireland	Irish Medicines Board	IMB
Israel	Institute for the Standardization and Control of Pharmaceuticals	ISCP
Italy	Agenzia Italiana del Farmaco	AIFA
Latvia	Zalu Valsts Inspectorura *(State Agency of Medicines)*	ZVA
	Liechtenstein Amt für Gesundheit *(Office of Healthcare)*	AG
Lithuania	State Medicines Control Agency	SMCA
Malaysia	National Pharmaceutical Control Bureau	NPCB
Malta	Medicines Authority Malta	MAM
Norway	Norwegian Medicines Agency	NOMA
Poland	Main Pharmaceutical Inspectorate	MPI
Portugal	Autoridade Nacional do Medicamento e Produtos de Saúde IP (National Authority of Medicines and Health Products IP)	INFARMED IP
Romania	National Agency for Medicines and Medical Devices	NAMMD
Singapore	Health Sciences Authority	HSA
Slovak Republic	State Institute for Drug Control	SIDC
Slovenia	Agency for Medicinal Products and Medical Devices	JAZMP
South Africa	Medicines Control Council	MCC
Spain	Agencia Española del Medicamento y Productos Sanitarios *(Spanish Agency of Drugs and Health Products)*	AEMPS
Sweden	Medical Products Agency	MPA
Switzerland	Swiss Agency for Therapeutic Products Swissmedic	
Ukraine	State Administration of Ukraine on Medicinal Products	SAUMP
United Kingdom	Medicines and Healthcare Products Regulatory Agency	MHRA
United States of America	United States Food and Drug Administration	US FDA

The next element of the System is the availability of the Inspectorate (inspection services) and the national Pharmacopoeia. Pharmacopoeia - a legal act that is legislative in nature and contains general requirements for drugs, pharmacopoeial articles (monographs), and methods of quality control of drugs. An important mechanism of integration of national systems of different countries is the European Pharmacopoeia (http://www.edqm.eu).

The texts of the European Pharmacopoeia (Ph. Eur.) concern the qualitative and quantitative composition of medicines, the tests to be carried out on medicines, on the raw materials used in the production of medicines and on the intermediates of synthesis. It contains texts covering substances, excipients and preparations for pharmaceutical use of chemical, animal, human or herbal origin, homoeopathic preparations and homoeopathic stocks, antibiotics, as well as dosage forms and containers. The texts also cover biologicals, blood and plasma derivatives, vaccines and radiopharmaceutical preparations. They are legally binding.

The European Pharmacopoeia is a single reference work for the quality control of medicines in the signatory states of the Convention on its elaboration. The official standards published within provide a legal and scientific basis for quality control during the development, production and marketing processes. They concern the qualitative and quantitative composition and the tests to be carried out on medicines, on the raw materials used in production of medicines and on the intermediates of synthesis. All producers of medicines and/or substances for pharmaceutical use must therefore apply these quality standards in order to market their products in the signatory states of the Convention.

Several legal texts make the European Pharmacopoeia mandatory. These are as follows:

- the Convention developed by the Council of Europe on the Elaboration of a European Pharmacopoeia,

- a Protocol adopted in 1994 and amending the Convention to prepare for the accession of the European Union and defining the respective powers of the European Union and its member states within the European Pharmacopoeia Commission,
- European Union Directives 2001/82/EC, 2001/83/EC, and 2003/63/EC, as amended, on medicines for human and veterinary use. These maintain the mandatory character of European Pharmacopoeia monographs when requesting marketing authorisation (MA).

The contracting parties of the Convention undertake to:

- progressively elaborate a Pharmacopoeia which shall become common to the countries concerned and which shall be entitled "European Pharmacopoeia"
- take the necessary measures to ensure that the monographs shall become the official standards applicable within their country by direct implementation in the national legislation or by indirect implementation through national translation.

36 Member States and the European Union are signatory to the Convention on the Elaboration of a European Pharmacopoeia. 8 European countries, 16 non-European countries and the World Health Organization (WHO) are observers (Scheme 9.3).

European Pharmacopoeia Members: Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, "the former Yugoslav Republic of Macedonia", Turkey, United Kingdom, and the European Union.

Last membership: Poland (2006)

European Pharmacopoeia Observers: Albania, Algeria, Argentina, Armenia, Australia, Belarus, Brazil, Canada, China, Georgia, Israel, Kazakhstan, Madagascar,

Malaysia, Moldova, Morocco, Republic of Guinea, the Russian Federation, Senegal, Singapore, Syria, Tunisia, Ukraine, the United States of America and the World Health Organization (WHO).

Last observerships: Republic of Guinea and The Health Sciences Authority (HSA) of Singapore (2012), Argentina, Armenia and Moldova (2008), Republic of Belarus (2007), the Russian Federation and Kazakhstan (2006).

Figure 9.1. European Pharmacopoeia Members and Observers, 2012*

* http://www.edqm.eu/en/List-of-PhEur-Members-Observers-1023.html

A significant number of European Pharmacopoeia monographs play in the national pharmacopoeias of European countries, such as the German Pharmacopoeia (Dentsches Arzneibuch), French Pharmacopoeia (Pharmacopee Francaise), British Pharmacopoeia etc. European Pharmacopoeia is obligatory for use in countries that

are signatories to the Convention (European Pharmacopeial Convention) and has a priority position in accordance with National Pharmacopoeia.

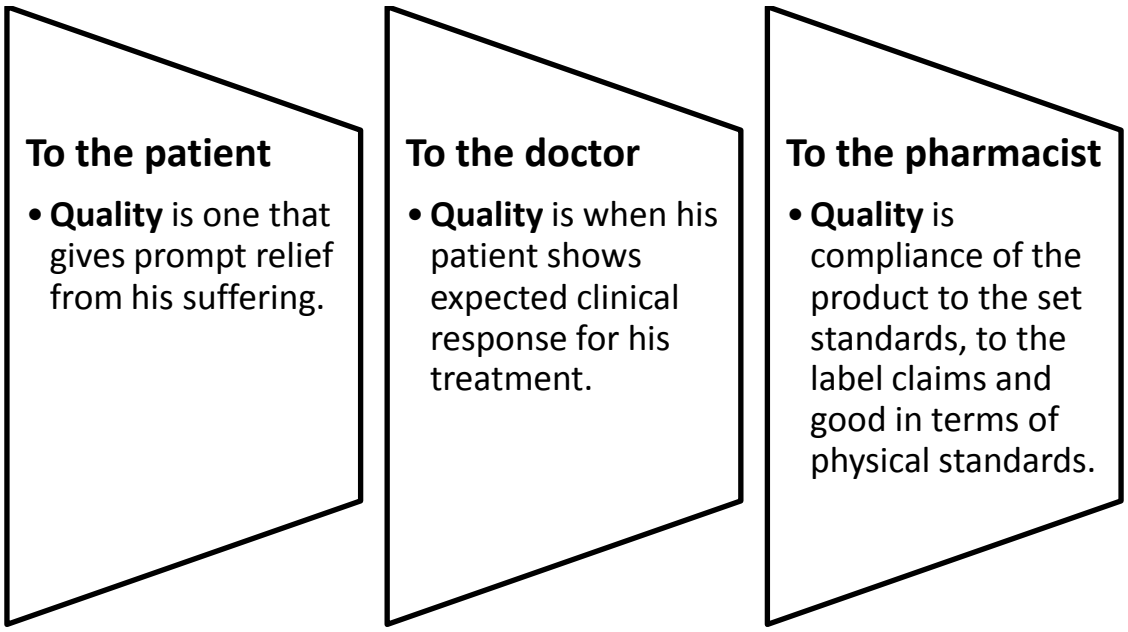
Ukraine also has a National Pharmacopoeia that was introduced October 1, 2001. Pharmacopoeia requirements are mandatory for all enterprises and institutions of Ukraine regardless of their ownership, which produce, store, control and use drugs. State Pharmacopoeia of Ukraine has the legislative character and harmonized with the European Pharmacopoeia.

The next elements of the System that directly affect the efficiency of its operation, is the *state registration* and *certification* of medicines, *licensing* of pharmaceutical activity. In order to register drugs in the System must operate the Authorities with developed and validated procedures, scientific expert assessment of quality of drugs. Moreover, the Authority shall exercise advisory and information activities aimed at protecting the pharmaceutical market of dangerous and substandard products. In Ukraine, as the competent Authority is the State Expert Center MoH Ukraine (www.pharma-center.kiev.ua).

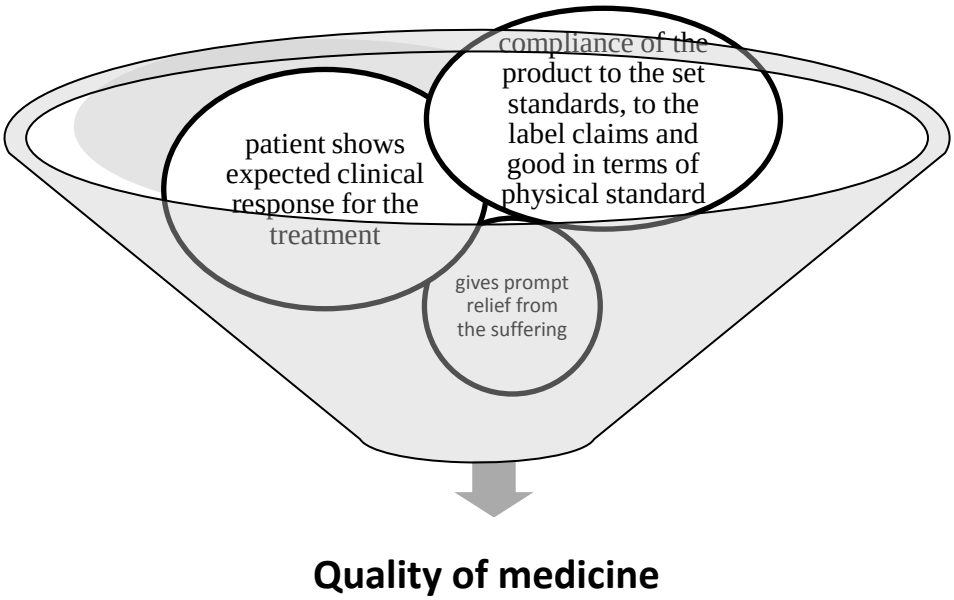
Significant potential for developing the pharmaceutical industry requires constant improvement of mechanisms to ensure quality of drugs and, consequently, improve the efficiency of the System. Therefore, an important component of public policy in health care should be measures taken to increase the quality requirements of drugs and pharmaceutical services provided by the public.

The quality of drugs is a set of properties that provides the ability to meet the needs of drug users according to their purpose and meet the requirements established by law.

If define the ‘Quality’ under a measurable parameter, the perception on ‘Quality’ will be different for different users (see scheme 9.4):



Scheme 9.3. 'Quality' under the different user's point of view



Scheme 9.4. Components of the term "Quality of medicine"

The first and the second ones are only the desires and abstract expressions that cannot be measured and assessed accurately. They can be called 'Therapeutic quality'. The third one is the most reliable, reproducible scientific parameter and hence is an universally accepted standard. This is called 'Pharmaceutical quality'.

Under active development of the pharmaceutical market as the problem of drugs is most urgent. First of all, this is due to the advent on the pharmaceutical market of counterfeit, substandard drugs, or drugs that have not passed the procedure

of state registration in the national health care system. Turnover of these drugs first, is a direct threat to public health, and sometimes people's lives, and secondly, results in significant financial losses legal manufacturers of drugs. That is, the presence of the pharmaceutical market of counterfeit, substandard and unregistered drugs is an essential socio-economic and medical-pharmaceutical problem.

The essence of the terms "counterfeit drugs", "defective / substandard", "unchecked" drug under the editorship of the WHO and domestic regulatory framework is presented in table. 9.2.

Table 9.2

Meaning of the terms counterfeit, substandard and unregistered medicine*

Term	Meaning
Counterfeit medicine	pharmaceutical product gives a false representation of its identity and/or source and/or record keeping for traceability; pretends to have been assessed and approved by the competent regulatory authority, pretending to be a genuine quality product; has an intention to deceive by a fraudulent activity; is falsified for profit motives, disregarding public health and safety; and that disputes concerning patents or trademarks must not be confused with falsification of medical products. *Medicine that deliberately marked with non-identical (not in) information (one or more of them) of drugs with the appropriate name included in the State Drugs Register of Ukraine, as well as drugs, deliberately forged in a different way, and does not correspond to the information (one or more of them), including composition of drugs with the appropriate name included in the State Drugs Register of Ukraine.**
Substandard medicine	pharmaceutical product that do not meet its quality standards and specifications. Each pharmaceutical product that a manufacturer produces has to comply with quality assurance standards and specifications, at release and throughout its shelf-life, according to the requirements of the territory of use. Normally, these standards and specifications are reviewed, assessed and approved by the applicable national or regional medicines regulatory authority before the product is authorized for marketing." (45th WHO Expert Committee on Specifications for Pharmaceutical Preparations, 2010). *Drug that is made by legal manufacturer with the correct labels, but that during production, transportation, storage lost compliance with the approved analytical documentation.**
Unregistered medicine	*Drug that did not pass the procedure of state registration with the relevant authorities and not included in the State Drugs Register.**

* *according to the Law of Ukraine of 09.08.2011, № 3718-VI «On Amendments to Certain Legislative Acts of Ukraine on prevention of fraud medicines," Order of the*

Ministry of Health of Ukraine of 30.10.2001, № 436 "On Approval of Agenda User quality control of drugs at wholesale and retail trade. "

The counterfeiting of medicines has developed into an industry that kills hundreds of thousands of people a year and can be associated with a form of organized crime. Counterfeit medicines affect 10% of the world medicines market and the losses are estimated at about 500 billion Euros a year. The consequences of counterfeiting are genuine damage to public health, the economy and society as a whole.

One of the latest threats facing the global pharmaceutical industry and healthcare is the presence of spurious/substandard drugs in the market. The WHO estimates that counterfeit drugs account for approximately 5-8% of the total worldwide trade in pharmaceuticals. According to the WHO, 'a counterfeit drug is one which is deliberately and fraudulently mislabeled with respect to identity, composition, and/or source.' This definition of counterfeit includes not only completely fake drugs but also those that have been tampered with, adulterated, diluted, repackaged, or relabeled so as to misrepresent the dosage, origin, or expiration date, as well as those substandard drugs that are cheaply produced in order to make unlawful profits. The Center for Medicine in the Public Interest (USA) estimates that sales in counterfeit pharmaceuticals will reach US $75 billion in 2010.

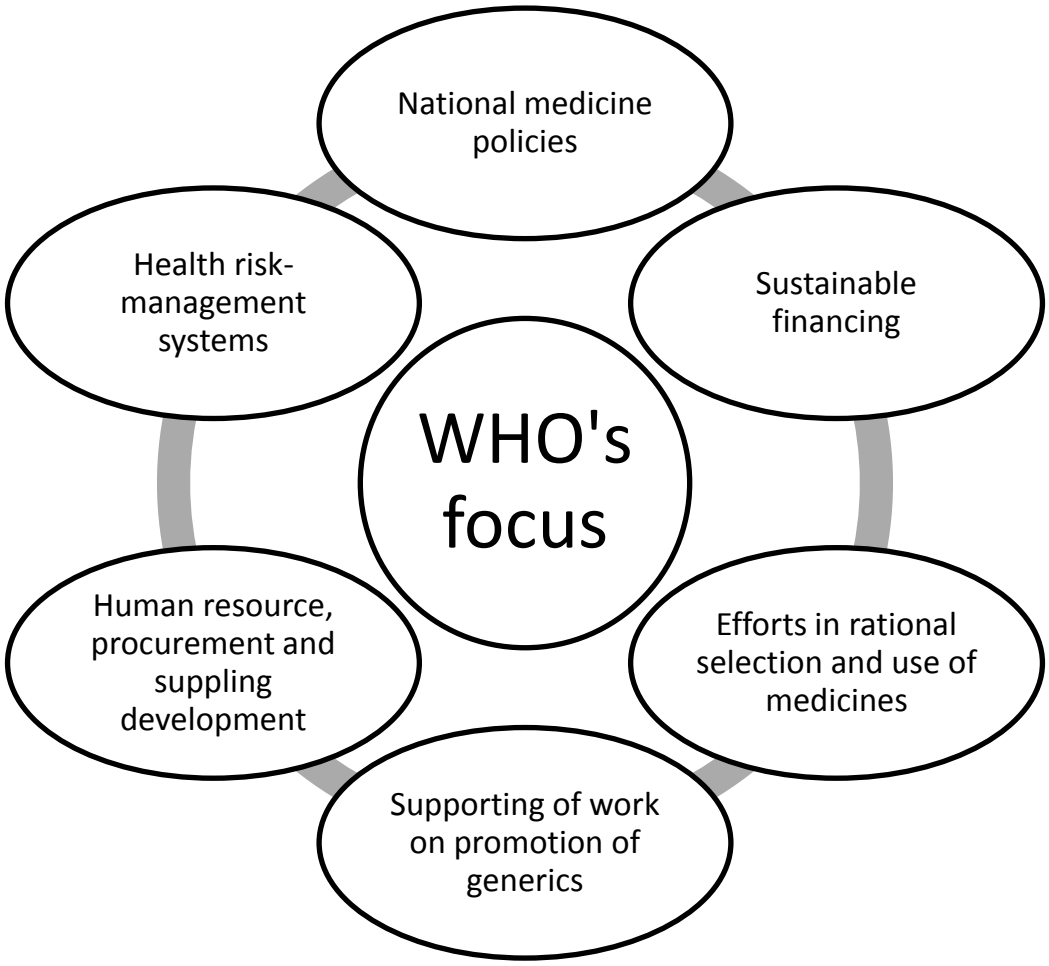
Leaders in drug fraud are underdeveloped African countries, where pharmaceutical products almost half consist of fakes. "Rating" of producing counterfeit according to the European Business Association (EBA): in Asia produced 62.9% of counterfeit drugs (35% - in India, 13.3% - Pakistan in other countries of the region - 14.6%). Among the pharmacotherapeutic groups often are forged antimicrobial drugs (28% of items), hormones (22%), antihistamine drugs (17%), vasodilatory drugs (7%), products consumed in sexual disorders (5%).

WHO reports show that substandard drugs are available in the market worldwide. These reports are not only from the poor or developing countries but also from the developed world. However, this problem is much more severe in developing countries than in countries such as the US, UK, Canada, and other industrialized

countries. In 2000, the health ministry in Russia reported that 56 drugs were counterfeit. The following year, approximately 3.6% of all pharmaceuticals in Russia were found to be fake. The US FDA reported that in spite of stringent controls, the number of cases of counterfeit drugs had increased in 2011 compared to the number of cases five years earlier. (http://www.ijp-online.com/article.asp?issn=0253-7613;year=2007;volume=39;issue=4;spage=206;epage=207;aulast=Khan)

WHO's role in the prevention and control of medical products of compromised quality, safety and efficacy such as substandard/spurious/falsely-labelled/falsified/counterfeit medical products from a public health perspective, excluding trade and intellectual property considerations.

WHO should continue to focus on and intensify its measures to make medical products more affordable, strengthening national regulatory authorities and health systems (see scheme 9.5).



Scheme 9.5. WHO's focuses in medicines QA field

In each of these areas, WHO's function should be: information sharing and awareness creation; norms and standards and technical assistance to countries on situation assessment; national policy development; and capacity building, supporting product development and domestic production.

Example of international collaboration in questions of QA of medicines is Europe Medicrime Convention. Thus on October 28th 2011 3 more countries join the Council of Europe Medicrime Convention (18/01/11), 12 countries paved the way for the implementation of the Medicrime Convention by signing the first international treaty which establishes as offences the manufacturing, the supplying and the trafficking of counterfeit medical products. Since then, 3 countries have joined them: Liechtenstein (4/11/2011), Luxembourg (22/12/2011) and just recently Denmark (12/1/2012).

Its important to understand the future role of WHO in the areas of substandard and spurious/falsely-labelled/falsified/counterfeit medical products under three headings, as shown at scheme 9.6.

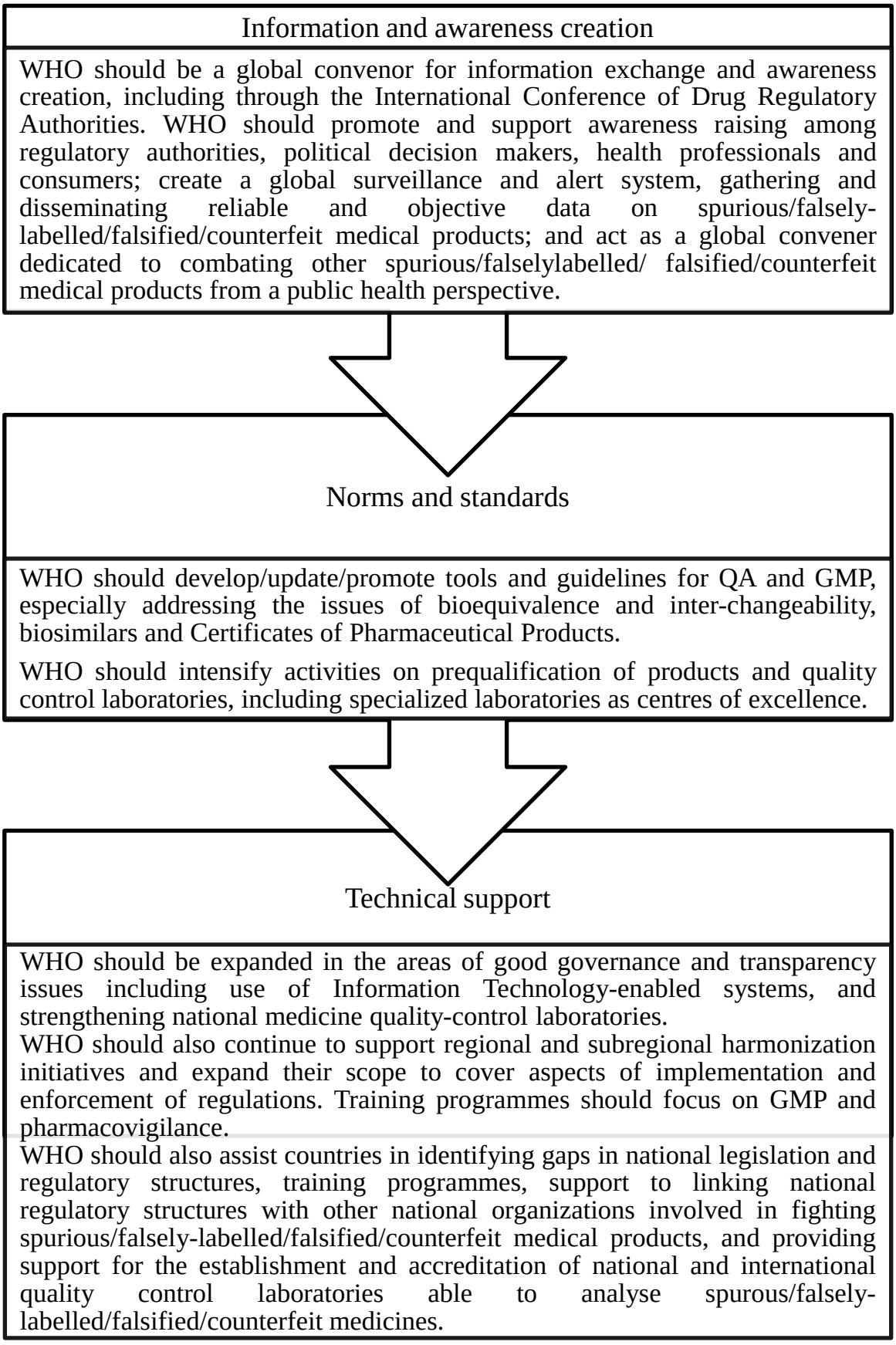
WHO has developed a program to assist national health system to prevent the circulation of counterfeit, substandard, unregistered drugs, which includes:

- a global database of these cases, detection of drugs;
- practical advice on methods of detection of counterfeit, substandard, unregistered drugs;
- a network of skilled employees in 110 countries, working in special institutions to ensure quality control in national health systems.

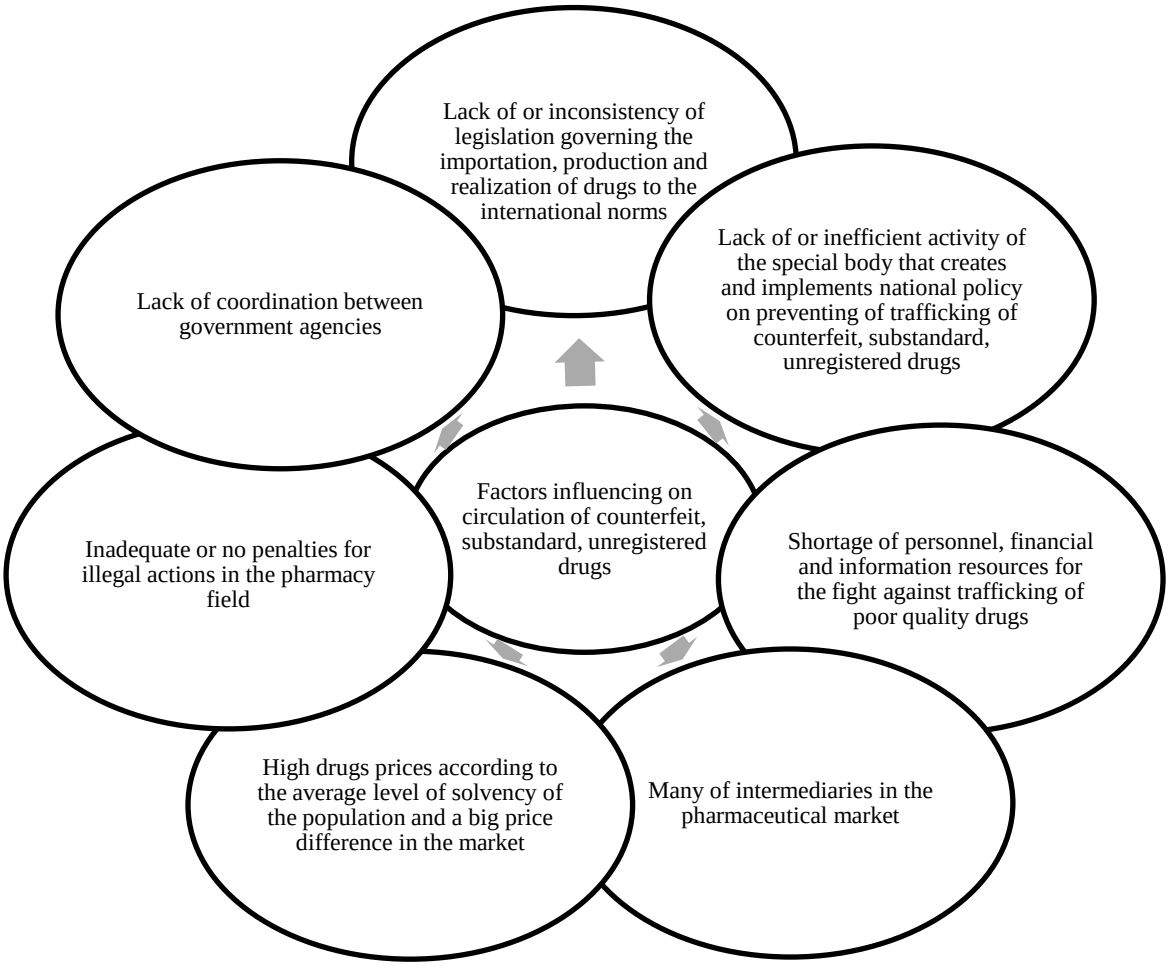
Despite the active combating counterfeit, substandard, unregistered drugs from international organizations and national Authorities cases of appearance of the pharmaceutical market ever recorded. This fact is typical for developed countries and for countries where the manufacture, import, wholesale and retail sale of drugs not controlled by the state. Clearly, the extent of manifestation of these phenomena are different, but WHO experts note that the appearance of counterfeit, substandard, unregistered drugs is characterized by both legal (developed countries) and illegal (transition countries) channels of outspread of pharmaceutical products.

The factors contributing to traffic of counterfeit, substandard, unregistered drugs are shown on the fig. 9.7.

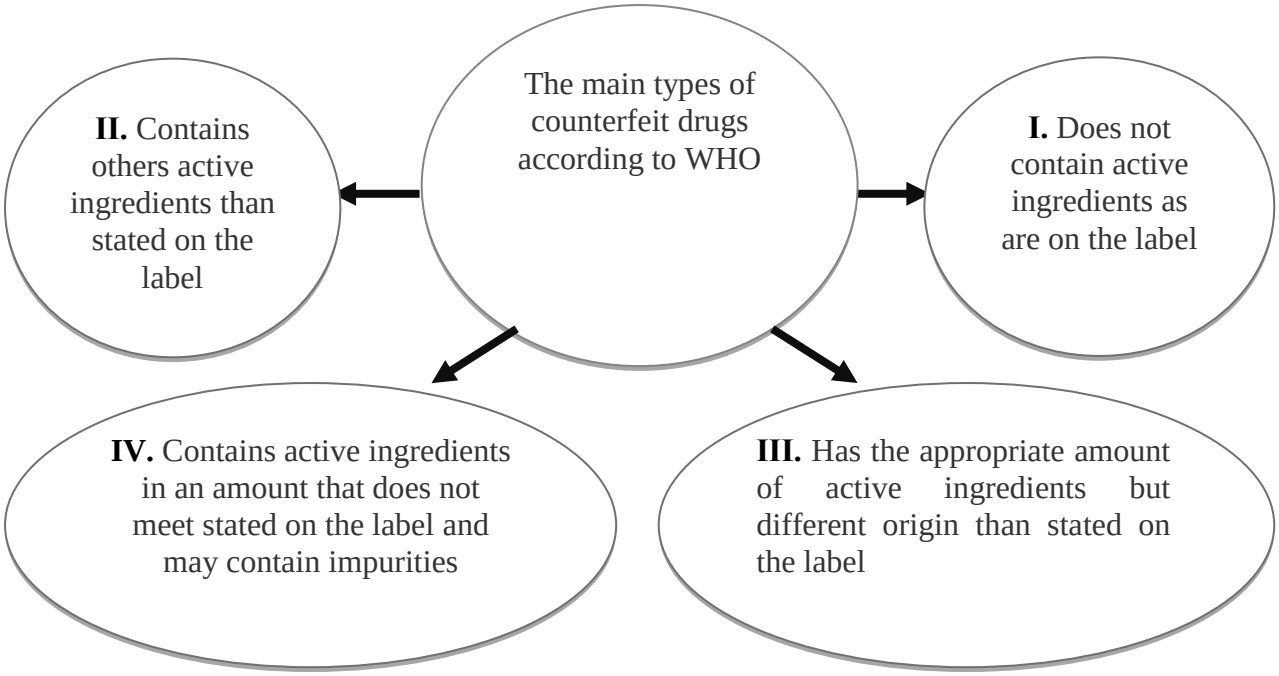
Currently there are four types of counterfeit drugs (Scheme 9.8). According to the information base WHO largest share in the structure of counterfeit drugs are drugs that contain no active ingredient (I-and type), then - counterfeit drugs that were inappropriate amount of active ingredients and undeclared active ingredients (**Scheme** 9.9).



Scheme 9.6. Future role of WHO in the areas of substandard and spurious/falsely-labelled/falsified/counterfeit medical products

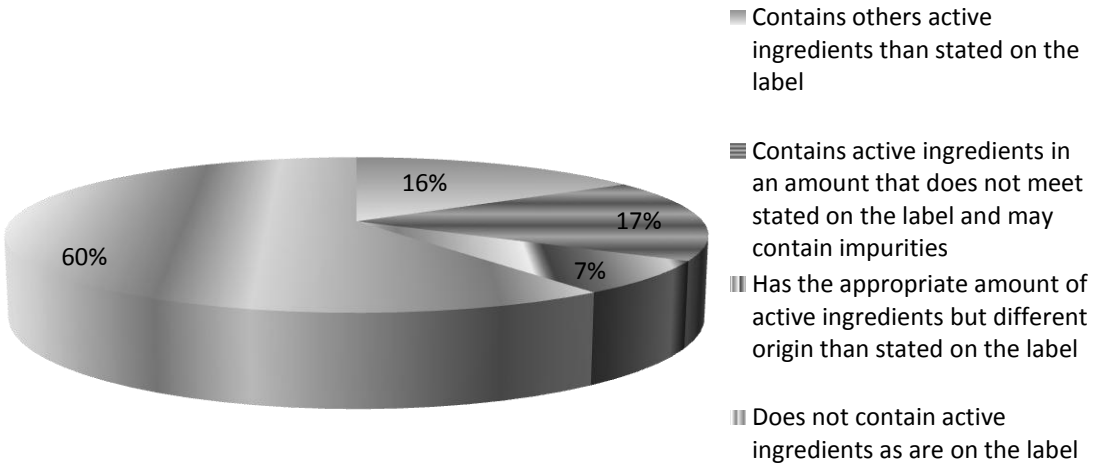


Scheme 9.7. Factors influencing on circulation of counterfeit, substandard and, unregistered drugs



Scheme 9.8. Classification of counterfeit medicines

The problem of prevention of trafficking of counterfeit, substandard and unregistered drugs at both the international and national levels is remains open and becomes every year more and more important.



Scheme 9.9. Distribution of counterfeit drugs in the pharmaceutical market in accordance with the information base WHO

9.2. Sertification of mediines quality

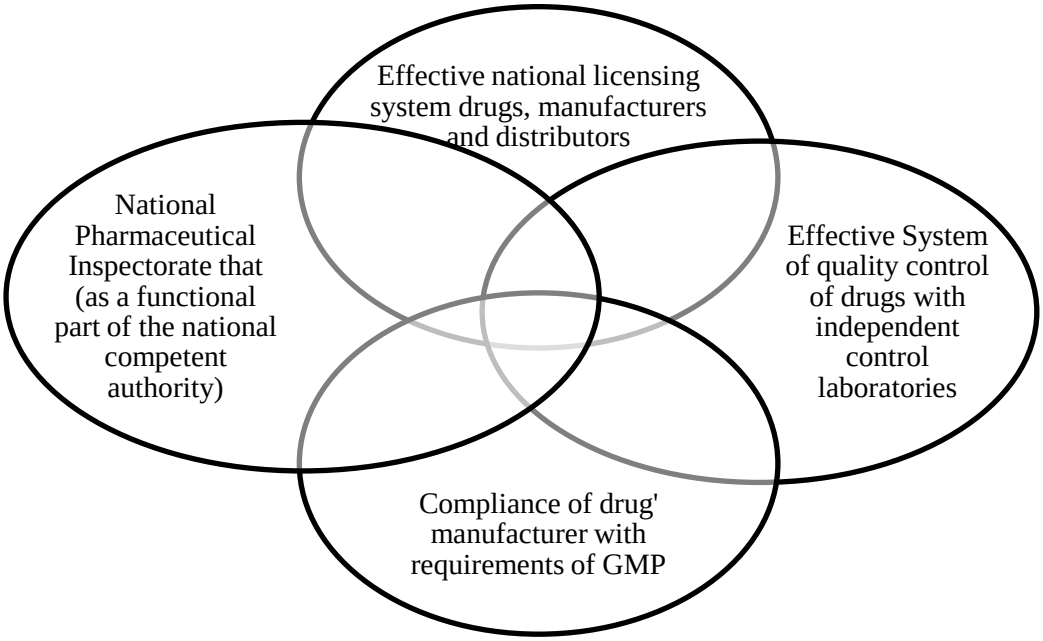
A comprehensive system of quality assurance must be founded on a reliable system of licensing and independent analysis of the finished product, as well as upon assurance obtained through independent inspection that all manufacturing operations are carried out in conformity with accepted norms, referred to as "good manufacturing practices" (GMP).

In 1969, the Twenty-second World Health Assembly, by resolution WHA22.50, endorsed requirements for Good Practices in the Manufacture and Quality Control of Drugs (referred to henceforth as "GMP as recommended by WHO"). These comprise internationally recognized and respected standards that all Member States are urged to adopt and to apply.

Certification - a set of measures during which the third (independent party) give a written guarantee that the product, process or service meets the approved requirements. World Health Assembly at the 50th session in 1996, urged all countries

to use the Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce**.**

The components of the WHO's Certification System are shown at scheme 9.10:



Scheme 9.10. The components of the WHO's Certification System

Three documents can be requested within the scope of the certification in QA of drugs (according with PIC/S):

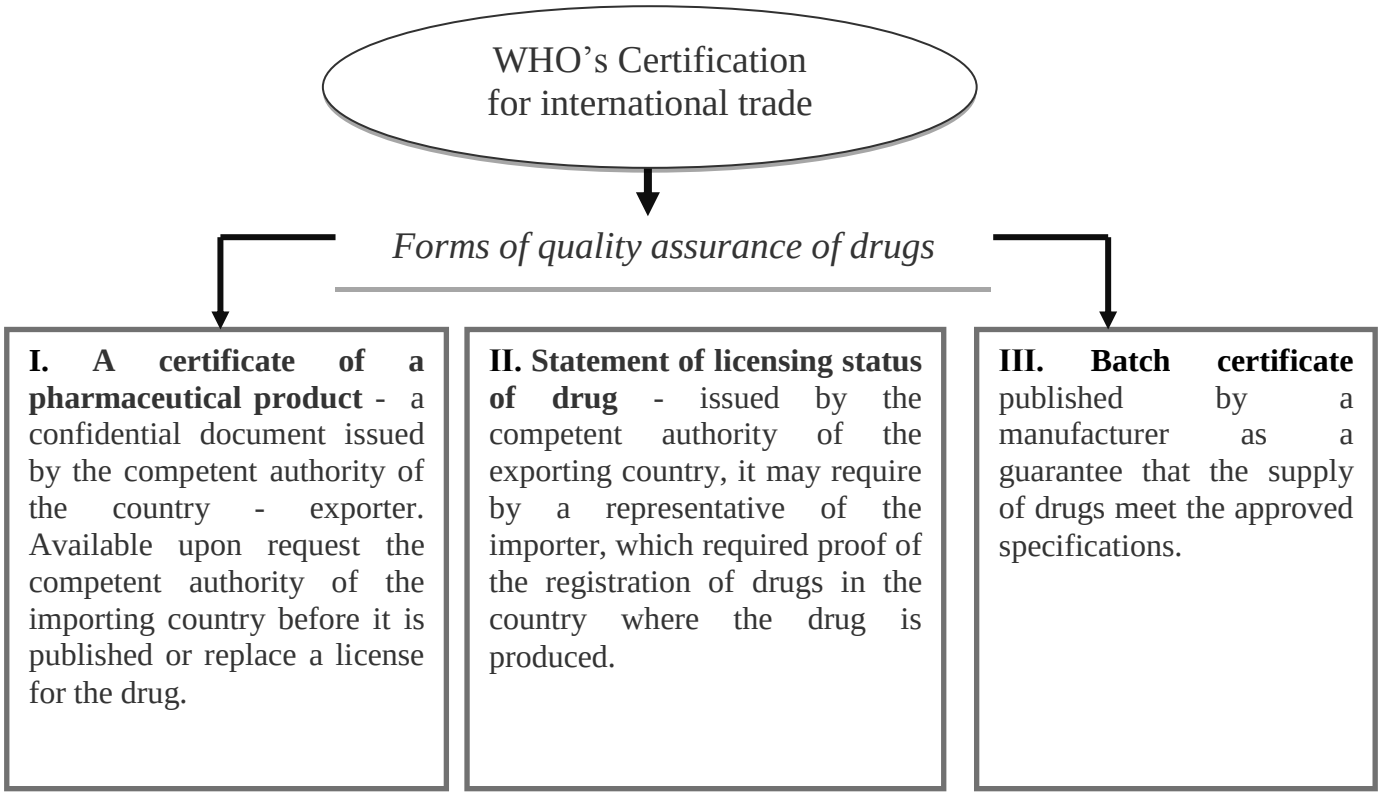
- A certificate of a pharmaceutical product (product certificate)
- A statement of licensing status of pharmaceutical product(s)
- A batch certificate of a pharmaceutical product (Scheme 9.11)

All participating countries are henceforth urged to adopt these formats to facilitate interpretation of certified information. Requests for the provision of certificates offering more limited attestations for instance, that the manufacturer complies with GMP or that the product is authorized for "free sale" within the country of export are discouraged. Similarly, requests should not be made for certification of information going beyond the scope of this Scheme. When manufacture takes place in a country other than that from which the product certificate is issued, an attestation relevant to compliance of the manufacture with GMP may still be provided (as an attachment to the product certificate) on the basis of inspections undertaken for registration purposes.

Pharmaceutical product: Any medicine intended for human use or veterinary product administered to food-producing animals, presented in its finished dosage form or as an active ingredient for use in such dosage form, that is subject to control by pharmaceutical legislation in both the exporting state and the importing state.

Pharmaceutical Product certificate: a document containing the information about medicine and that is validated and issued for a specific product by the competent authority of the exporting country and intended for use by the competent authority in the importing country or - in the absence of such an authority - by the drug procurement authority. Certificate issued by the exporting country, is intended for use by the competent authority within an importing country in two situations:

- when the product in question is under consideration for a product license that will authorize its importation and sale;
- when administrative action is required to renew, extend, vary or review such a license.



Scheme 9.11. A characteristic of forms of medicines quality assurance in the WHO Certification System

All requests for certificates should be channelled through the Inspector in the importing country and the product license holder or other commercially-interested party in the exporting country ("the applicant").

Statement of Licensing Status: This attests only that a license has been issued for a specified product, or products, for use in the exporting country. It is intended for use by importing Inspectors when considering bids made in response to an international tender, in which case it should be requested by the Inspector as a condition of bidding. It is intended only to facilitate the screening and preparation of information. The importation of any product that is provisionally selected through this procedure should be determined on the basis of a Certificate of a Pharmaceutical Product.

Batch certificate: A document containing information about medicine, will normally be issued for each batch by the manufacturer. Furthermore, exceptionally a batch certificate may be validated or issued by the Competent authority of the exporting country, particularly for vaccines, sera and other biological products. The batch certificate travels with every major consignment

One more document thatis important to assure quality of medicine on international level - *Product license:* An official document issued by the competent drug regulatory authority for the purpose of marketing or free distribution of a product. It must set out, inter alia, the name of the product, the pharmaceutical dosage form, the quantitative formula (including excipients) per unit dose (using international nonproprietary names or national generic names where they exist), the shelf-life and storage conditions and packaging characteristics. It also contains all information approved for health professionals and the public (except promotional information), the sales category, the name and address of the license holder, and the period of validity of the license.

The examples of Morocco domestic documents of QA of medicines are shown below.

Royaume du Maroc

Office National de l'Eau Potable

ONEP

Pour recevoir une réponse adaptée à vos attentes, veuillez remplirce formulaire et le faxer au n° **037.75.91.09**

Destinataire : Direction Contrôle de la Qualité des Eaux

Personnes à contacter pour toutes informations : Mmes Djekmani et /ou Bekkali

Vos références

Vous êtes un :……

Particulier ( ) Laboratoire ( ) Entreprise ( ) Autres ( )……
……
……
.....
.Nom / Fonction du contact :
.....
……
E-mail :
……
Adresse.....……

.....…Ville : ….....….....
Tél. : ……..…….....……
Fax :……..

Domaine d'activité :
…….....…….....**....**
……
……
Etes-vous un ancien client ? Oui ( ) Non ( )
.....

Si oui : Numéro du devis/facture précédent(e) : **....**.….....en date du :
.....

Êtes-vous le payeur ? Oui ( ) Non ( )
Si non : coordonnées du payeur :
...……..
……

Votre interlocuteur sur place :
.....

Vos besoins en analyses d'eau

Type (matrice) d'eau :
Eau Traitée ( ) Eau Naturelle ( ) Eau usée/résiduaire ( )
Nature d'eau :
Eau de réseau ( ) Eau minérale ( ) Eau de Puits ( ) Eau de rivière ( )
Eau de Piscine ( ) Eaux de Baignade/Plage ( )
Autres (à préciser) :
.....
. Objectifs/buts des analyses demandées :
• Vérifier la potabilité de l'eau ( )
• Vérifier le respect de la réglementation en vigueur ( )
• Confirmer des résultats d'analyses ( ), Dans ce cas, indiquer :
.....
.....
……
……
- la qualité ou les caractéristiques de l'eau concernée, ...
.....
- les références de la première analyse : laboratoire, méthode (s) d'analyse utilisée (s) et éventuellement le (s) résultat (s) d'analyse (s) produite (s)
.....
……
Les prélèvements sont-ils à réaliser par les techniciens du laboratoire de l'ONEP ? Oui ( ) Non ( )
Si non, vos Inspectors sont-ils habilités à réaliser le prélèvement ? Oui ( ) Non ( ) Si non, le laboratoire de l'ONEP mettra à votre disposition les consignes à respecter pour réaliser le prélèvement et les flacons adaptés à chaque paramètre à analyser. Les résultats des analyses dépendront de l'échantillonnage, le prélèvement, le flaconnage, la conservation et le délai de réception de l'échantillon (s) par le laboratoire de l'ONEP.

Lieu de prélèvement	Nature de l'échantillon	Nombre d'échantillon	Fréquence	Analyses demandées	Date d'intervention souhaitée
Domicile	Ex : eau de puits			Relatives à la potabilité de l'eau de puits	.....
Usine	Ex : rejet industriel			Vérification réglementaire	.....

N.B : Veuillez préciser la référence de la de méthode d'analyse exigée éventuellement par vos soins.

المملكة المغربية

وزارة الصناعة و التجارة و التكنولوجيات الحديثة

شـــــهـــــادة الاعـــتـــمـــــاد

م م إيـــــزو 17025

يشهد وزير الصناعة و التجارة والتكنولوجيات الحديثة أن المختبر :

مديرية مراقبة جودة المياه

بالمكتب الوطني للماء الصالح للشرب

الواقعة ب: محطة المعالجة أبي رقراق، شارع محمد بن الحسن الوزاني، الرباط

معتمد وفقا للمواصفة المغربية :

م م إيـــزو 17025: 2005

لإجراء التجارب في الميادين المعرفة في القائمة رقم **AL 05/2004** المرفقة بـــهذه الشهادة

تمتد صلاحية هذه الشهادة الممنوحة وفق الشروط المحددة في المرسوم رقم 530.93.2 بتاريخ 20 شتنبر 1993 والدورية المتعلقة بشهادة الاعتماد لمختبرات التجارب و المعايرة إلى غاية **28 أبريل 2010.**

الرباط في 29 غشت 2008

وزير الصناعة و التجارة والتكنولوجيات الحديثة

أحمد رضى شامي

Ministère de l'Industrie, du Commerce et des Nouvelles Technologies

CERTIFICAT D'ACCREDITATION
NM ISO 17025

Le Ministre de l'Industrie, du Commerce et des Nouvelles Technologies atteste que le laboratoire :

DIRECTION DU CONTROLE DE LA QUALITE DES EAUX
DE L'OFFICE NATIONAL DE L'EAU POTABLE
Sis, Station de Traitement des eaux de Bouregreg,
Avenue Mohamed Bel Hassan El Ouazzani, Rabat

est accrédité conformément à la norme :

NM ISO 17025 : 2005

pour les prestations d'essais définies dans la portée d'accréditation AL 05/2004 annexée au présent certificat.

La présente attestation, délivrée dans les conditions fixées par le décret n° 2.93.530 du 20 Septembre 1993 et la circulaire relative à l'accréditation des laboratoires, est valable jusqu'au 28 Avril 2010.

Rabat, le : 29 Août 2008

Le Ministre de l'Industrie, du Commerce
et des Nouvelles Technologies

Signé : Ahmed Reda Chami

N° 695

CERTIFICAT D'ACCRÉDITATION
DE LABORATOIRE D'ANALYSE ENVIRONNEMENTALE

OFFICE NATIONAL DE L'EAU POTABLE (ONEP)
Direction Contrôle Qualité des Eaux
Station de traitement du Bouregreg, Route d'Akreuch
Rabat MAROC

Numéro de laboratoire : 902

Champs d'accréditation : Microbiologie de l'eau et des matières solides
Chimie de l'eau

Conformément aux normes et exigences du *Programme d'accréditation des laboratoires d'analyse environnementale* du ministère du Développement durable, de l'Environnement et des Parcs du Québec incluant celles de la norme internationale ISO/CEI 17025, le détenteur de ce certificat est habilité à réaliser les analyses déterminées dans les domaines précisés dans le document intitulé « Attestation de la portée d'accréditation ».

Date d'entrée en vigueur : 2004-09-23 Date d'échéance : 2009-12-31

Le présent certificat, valide pour la période indiquée, est soumis aux règles et procédures établies et demeure la propriété du Ministère.

La sous-ministre

Ministère du Développement durable, de l'Environnement et des Parcs
Québec

N° 901

CERTIFICAT D'ACCRÉDITATION
DE LABORATOIRE D'ANALYSE ENVIRONNEMENTALE

OFFICE NATIONAL DE L'EAU POTABLE (ONEP)
Direction Contrôle Qualité des Eaux
Station de traitement du Bouregreg, Route d'Akreuch
Rabat MAROC

Numéro de laboratoire : 902

Champ d'accréditation : Toxicologie de l'eau

Conformément aux normes et exigences du Programme d'accréditation des laboratoires d'analyse environnementale du ministère du Développement durable, de l'Environnement et des Parcs du Québec incluant celles de la norme internationale ISO/CEI 17025, le détenteur de ce certificat est habilité à réaliser les analyses déterminées dans les domaines précisés dans le document intitulé « Attestation de la portée d'accréditation ».

Date d'entrée en vigueur : 2007-11-01 Date d'échéance : 2012-10-31

Le présent certificat, valide pour la période indiquée, est soumis aux règles et procédures établies et demeure la propriété du Ministère.

La sous-ministre

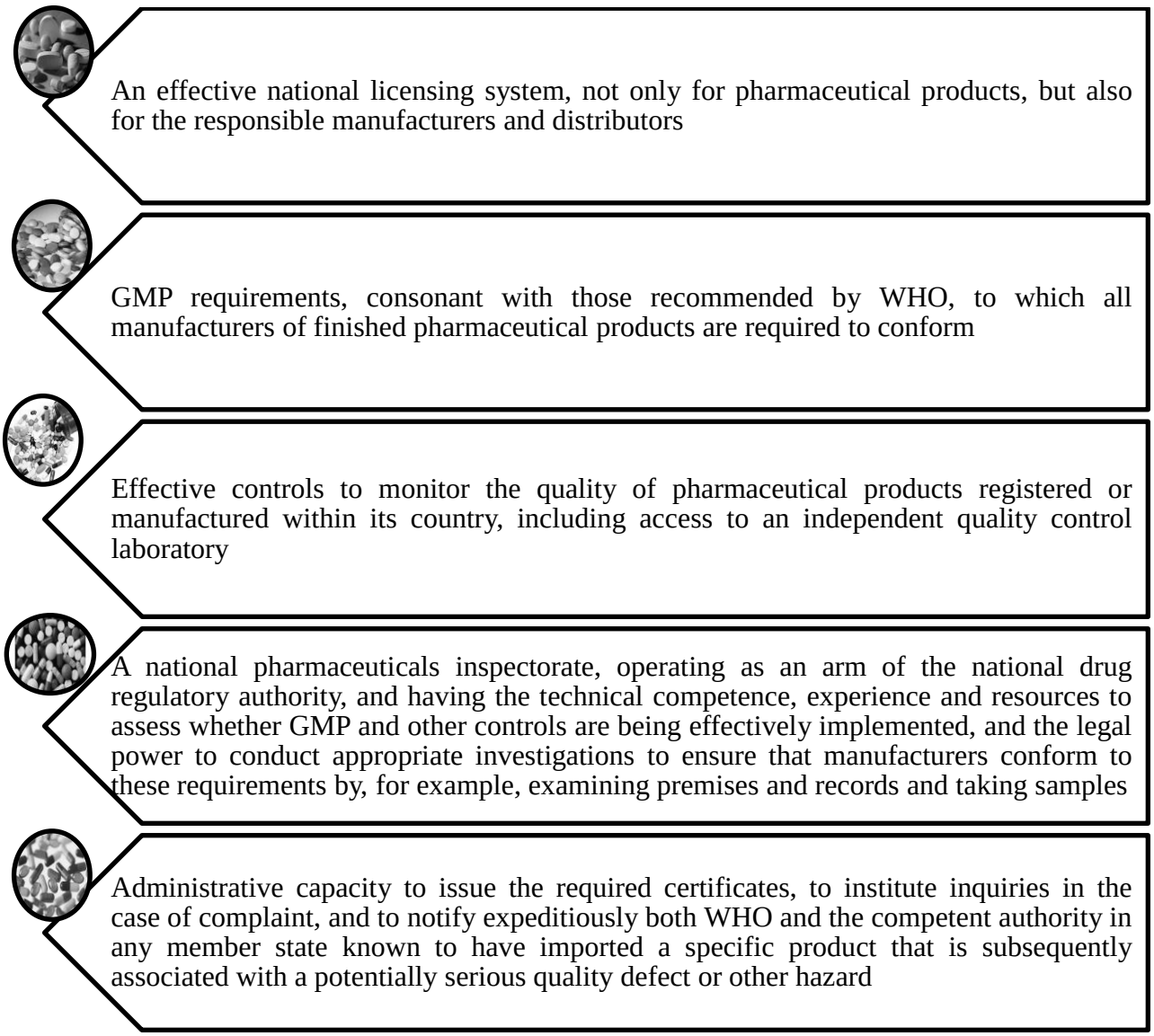
Ministère du Développement durable, de l'Environnement et des Parcs
Québec

http://www.iea.ma/

Certification procedure includes the following steps:

- Implementation of certification by the State Inspectorate
- Providing expert examination of certification dossier (a set of documents on drugs, which is required for issuance of certificate)
- Implementation of laboratory quality control of samples (if necessary); decision to issue the certificate
- Processing and issuance of certificate.

Countries all over the world are interested in development of exportation of medicines. There are several recommendations of PIC/S for effective export of pharmaceutical products (Scheme 9.12).

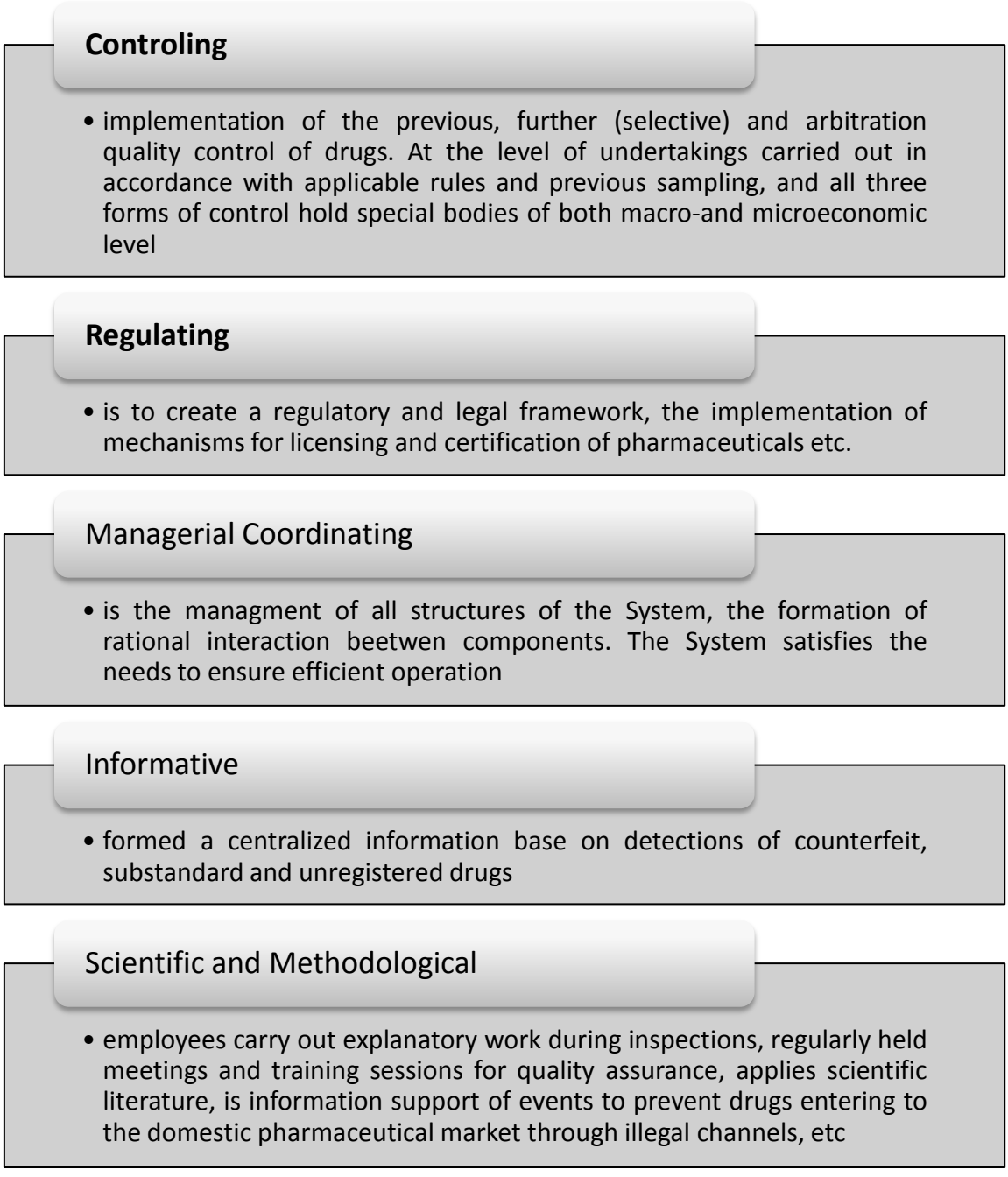


Scheme 9.12. Conditions for effective export of pharmaceutical products

In Ukraine, Ministry of Health of 14.01.2004, № 9 approved the procedure for certification of drugs for international trade based on the requirements of Directive 2001/83 European Parliament and EU Council and the recommendations of the World Health Organization WHO TRS N 823, 1992. Certification of drugs introduced in order to create conditions for the export of domestic drugs, evidence of their quality according to international standards and on a voluntary basis. In Ukraine, the document declares that the quality of drugs is certified by a producer. In the absence of licensing of manufacturers under the rules of GMP certificate unfortunately can’t guarantee the quality of drugs.

9.3. The organization of the State System of QA of medicines in Ukraine

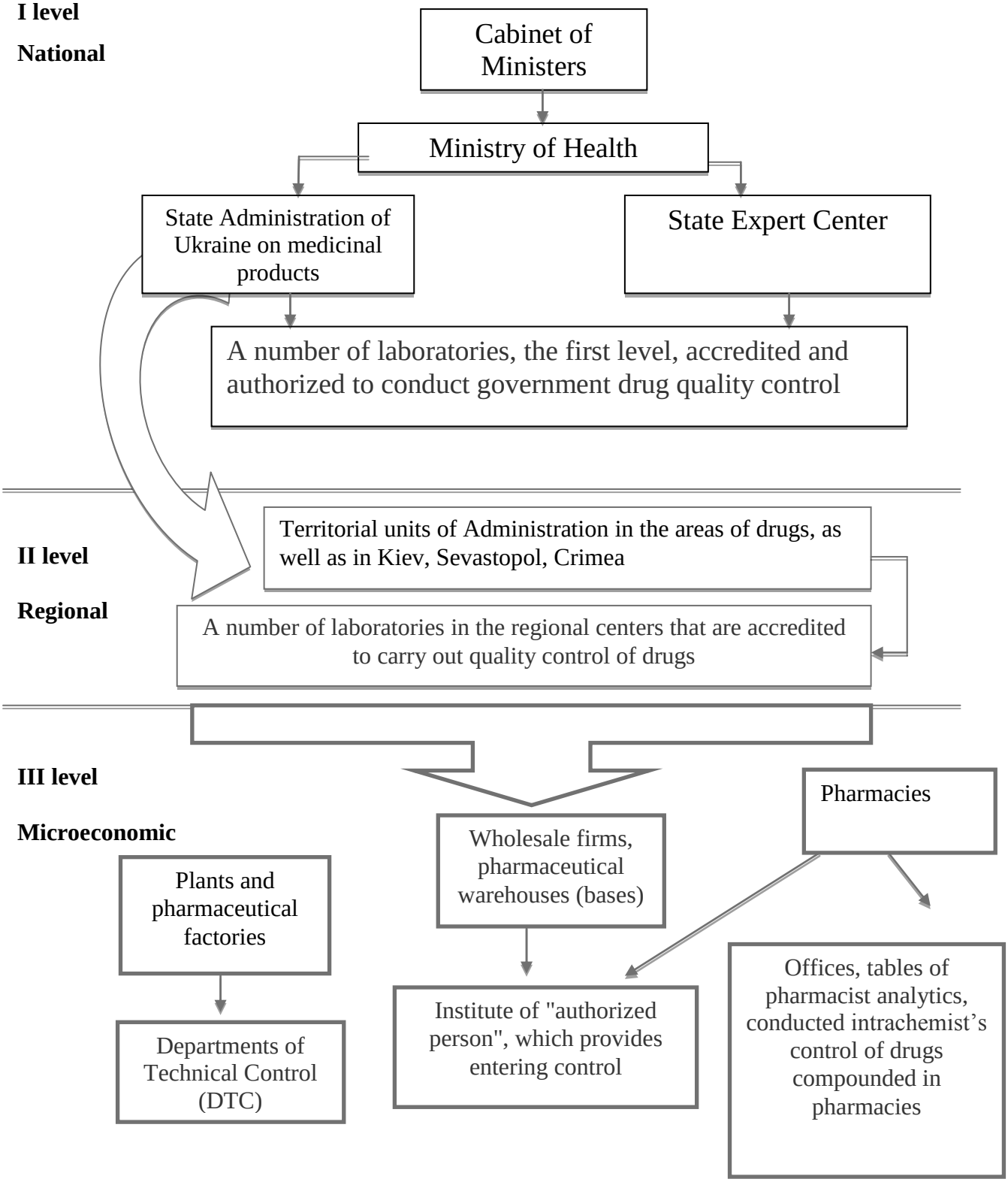
At the present stage of development of domestic pharmaceutical industry considered system is a complex state structure that is in dynamic development. The main objective of the System is to provide quality of substances, drugs from entry on the territory of Ukraine, production, transportation, storage, wholesale to retail sale. To solve the given task System performs the following functions (Scheme 9.13).



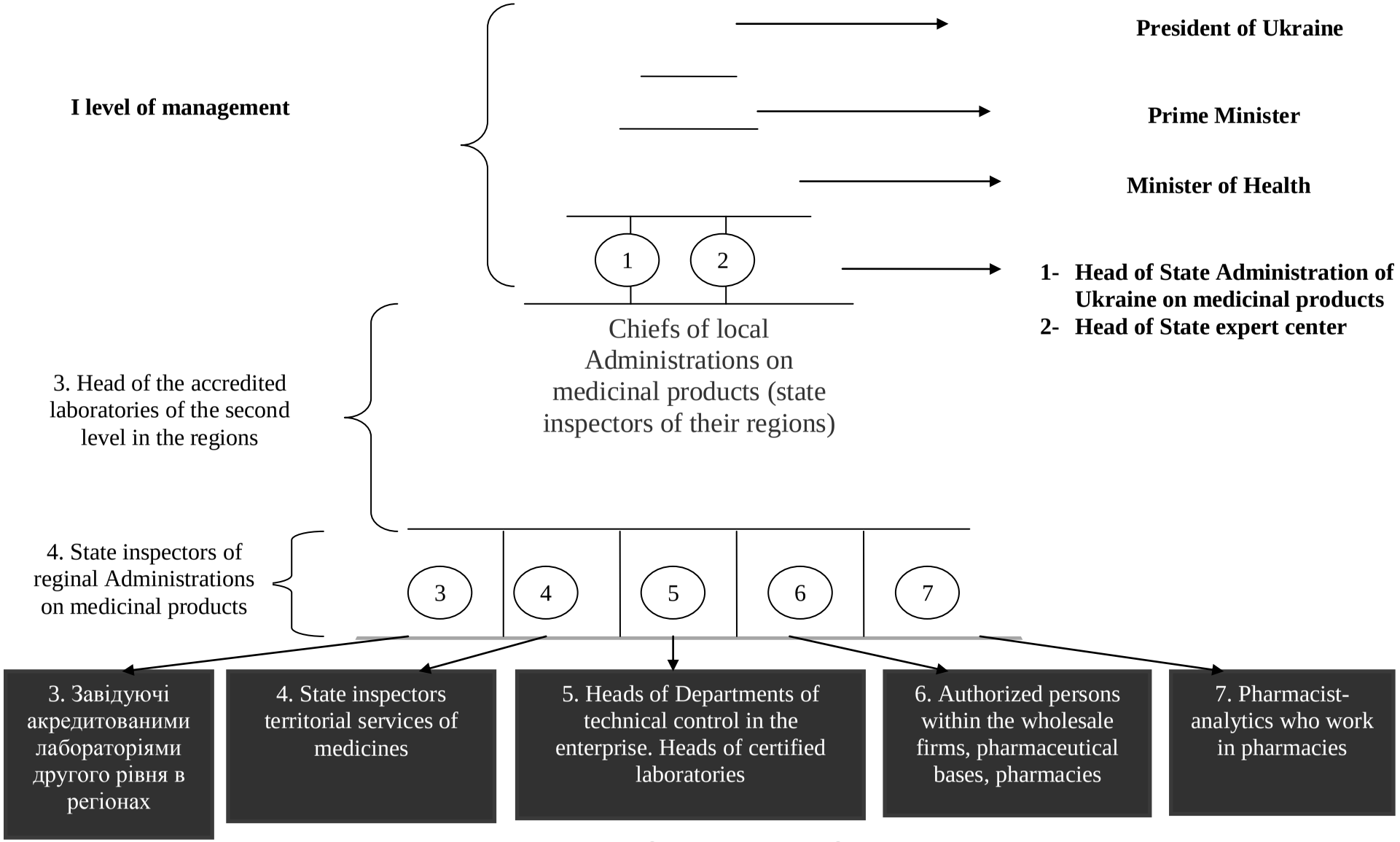
Scheme 9.13. Functions of the State System of QA

The existing System based on the principle of centralization of administrative subordination of constituents. Currently, the domestic system has three levels:

• National;
• Regional;
• Microeconomic (at businesses) (Scheme 9.14).



Scheme 9.14.Organization structure of state System of QA of medicines



Scheme 9.15. Structure of management of MQC System in Ukraine

Management System has three levels and is in the relevant regulatory and legal framework specific organs and structures of executive power (Scheme 9.15)

Main especial organ of the System is a State Administrations of Ukraine on medicinal products (http://diklz.gov.ua). Next state organ of QA of medicines System is a State Expert center (www.pharma-center.kiev.ua), which fulfills the following functions:

- expert;
- scientific;
- consulting;
- manufacturing;
- informative.

An important mechanism to protect the domestic pharmaceutical market of substandard products is a state registration of medicines. State register of medicines (http://www.drlz.kiev.ua) — document containing the list of permitted for usage medicines in Ukraine.

9.4. Organization of inspection of facilities and pharmaceutical industry

Implementation of state control of business entities regardless of ownership and subordination of quality drugs in the course of their production in pharmacies, wholesalers and retailers is one of the main tasks of the State Administrations and its territorial bodies in Ukraine.

Control over the observance of undertakings legislation to ensure the quality of drugs during their production, storage, transportation, sale and medical use is done by planning, subsequent inspections and audits on behalf of, carried out directly at the place of business activity.

The reason for testing is an order (decision) of territorial units of State Administrations, which listed the name of the entity, its location, the working group of inspectors of the term, character verification; check if the instructions - link to the

document under which it is organized. The decision (order) is printed on letterhead and certified by seal and signature of the chief of inspection or his deputy.

Planned test is comprehensive test of the entity according to the approved plan to observe the legal requirements for quality assurance of drugs during their production, wholesale and retail sale. It have to be held only once a year. Scheduled inspections of economic entities are territorial unit with all the attractions of drugs (with addresses) and submitted for approval to State Administrations quarterly.

The next test is conducted to monitor the implementation of measures to address violations and deficiencies identified by the preliminary routine check. Depending on the nature of the violations and the amount of work to be done to address them, the period of its implementation can be measured in time from 6 weeks to 6 months.

Check the instructions are:

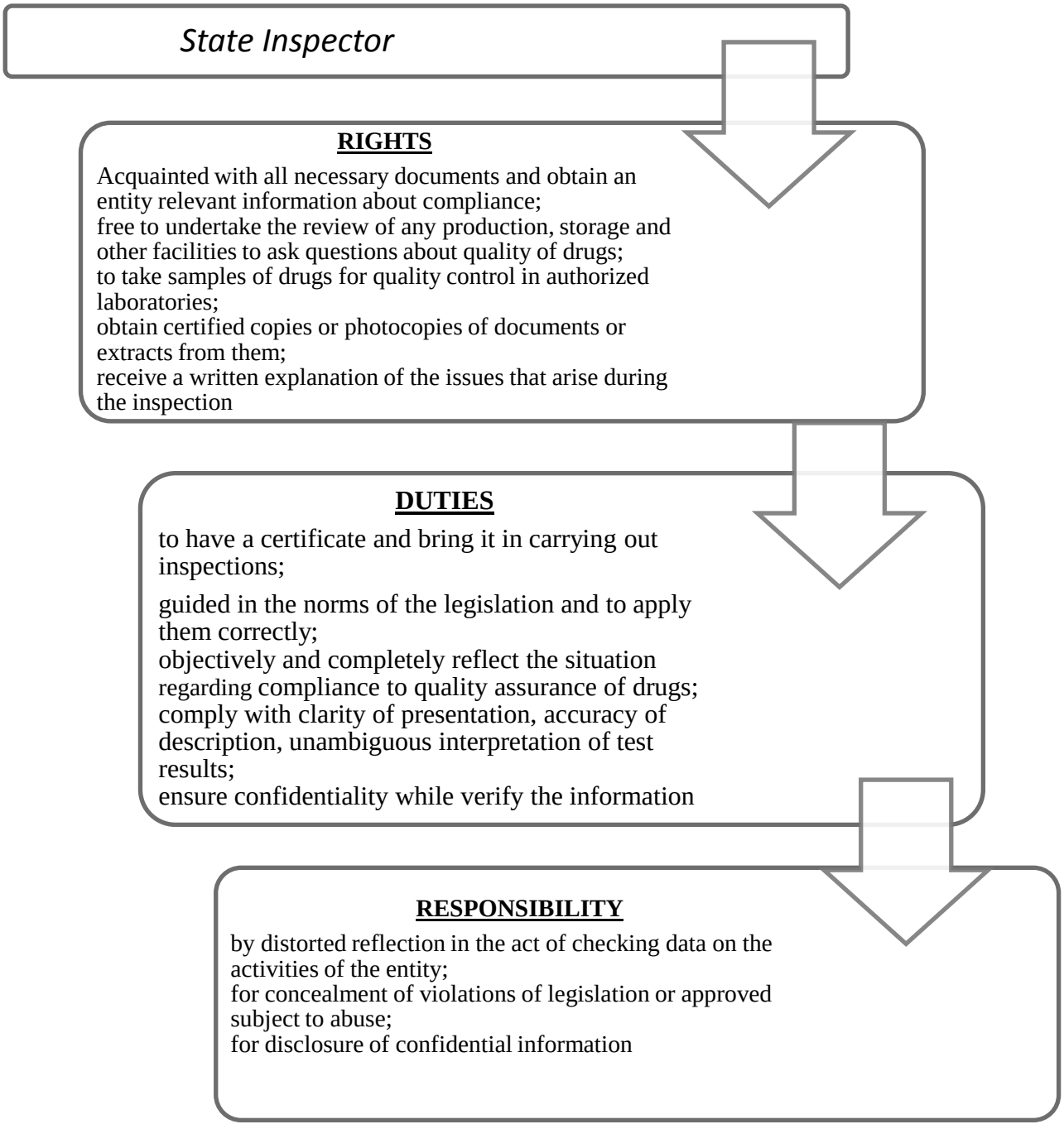
• by order State Administrations on the basis of income to her written statement (message) of the violation subject to legal requirements regarding quality assurance of drugs;

• on behalf of Parliament, the President, the Cabinet of Ministers of Ukraine, Ministry of Health of Ukraine or at the request or to request other state regulatory and law enforcement bodies and local authorities;

The test provides employee of the State Administrations or Territorial unit - the state inspector. If it is necessary inspection by the territorial agreement may involve audits of other state regulatory agencies or individual professionals who are required to carry out specific education, specialty and experience (the tax inspection, sanitation, etc.). Within its competence, they have the rights; perform the duties and responsibility (Scheme 9.16).

Key stages of inspection. Inspection begins with an analysis of documents related to the specific activity of the subject (manufacture of medicines in pharmacies, wholesale or retail). First, the inspector establishes the presence of the original permits: operating licenses for each of the activities of passports and pharmacy departments,

certificate of ownership or lease of facilities, charter, registration certificate. Must be checked such regulatory documents as an order to appoint an authorized person, the inner order of treatment drugs, emergency action plan.



Scheme 9.16. Rights, duties and responsibility of the State Inspector

Controlled maintenance of a register of drugs received or realized by the entity, the existence of the findings of the authorized person of the results of input control, accounting information found substandard, counterfeit or unregistered drugs. The

inspector checks the proper execution of contracts with suppliers and / or customers, availability of certified copies of licenses that prove their right to practice a particular pharmaceutical activity, the completion of supporting documents for drugs (indication in the name of the manufacturer overhead, a series of drugs, expiry date etc.). An original must provide health certificates for their vehicles and certified copies of transport supplier / buyer.

Then Inspector conducts inspection of existing business of manufacturing, warehouse, retail, ancillary facilities, establish their composition and size, line regulation and equipment requirements of regulations and processes that they have done. Checks for compliance with sanitary requirements and technical condition of equipment, establishes the timeliness of metrological validation of control and measurement.

Details monitored compliance with storage conditions and rules of the drugs, herbal drugs, pharmaceutical goods. The Special inspection procedures shall be deposited and the account of narcotic and psychotropic drugs, precursors. Inspector focuses on the rules of drug manufacturing technology, organization intrachemist's control, availability of all required logs and records chronologically in them, under the terms of use, external design and conditions of sterilization. Also check the accuracy of processing and storage vessels, appearance of employees, the state of work clothes, the timeliness of a medical checkup and more. The inspector must exercise control visual selective drugs, in which a series of checks, expiration date, registration status, integrity, uniformity, for damage, quality of packaging materials group, external and internal packaging, labeling, information leaflet form without disclosure package . If necessary, check with the disclosure of drug packaging on the size, shape, color, uniformity, number of units in the package, the presence of contamination.

For each series of drugs that are in the implementation, the inspector can check the availability of supporting documents and certificates as a producer. He also checks the contents of the most selective certifications.

After the inspection the inspector finally analyzes the received data and decides which ones do not meet the requirements and must be submitted as non-compliance. It provides documentation of their final act as a check, the order of assembly is established by the order MHC of Ukraine from 26.10.2001, № 428. The act made in duplicate and signed by the inspector and the person in the presence of a test carried out. One copy remains in the entity, the second - the inspector passes to the territorial units or State Administration. The Act must include the documents and materials that were received during the inspection and confirm the objectivity of shared data. In case of refusal of the subject from signing the act is motivated from the corresponding note explaining the reasons.

With the agreement of the head after making the act made the final meeting, which involved the inspector and all involved in the inspection staff. It comprehensively discusses the results of inspection and controversial issues are resolved. Inspector informs the present list of deficiencies and violations of basic norms and concludes on the status of quality drugs in the subject. It must also notes positive aspects that can be used for exchange of experience, training.

9.5. Organization of entrance quality control of drugs and medicinal goods entered to pharmacies, pharmaceutical companies

Pharmacy bases, stores, wholesalers, pharmacies various forms of ownership should provide entrance control in full. To do this, by the manager should be appointed Inspector (Authorized Persons), the proper performance of duties which guarantees the quality of drugs and medicinal goods coming to the entities. An authorized person must have higher pharmaceutical education and experience not less than 2 years. Its jurisdiction shall prepare and issue an opinion on the results of the entrance series of quality control of drugs received by the institution, with a note of the possibility of transmission to their implementation. An authorized person performing the following duties:

- incoming quality control of drugs, including test:
  - appearance of drugs and its visual inspection;

- accompanying documents-invoices, which must contain the name, dosage, dosage form, batch number, quantity, name of the manufacturer of each drug;
- certificate as manufacturer certified by the seal of the last supplier;
- information about state registration of drugs;
- a report incoming quality control of drugs;

• keeping a register of drugs that are received by the business entity that will allows you to track the source of any unsafe or counterfeit drugs party;

• keeping a register of drugs that are sold business entity, allowing, if necessary, to withdraw identified batch of counterfeit or substandard drugs (for wholesale organizations);

• check for substandard and counterfeit medicines series reportedly State Administrations and territorial services;

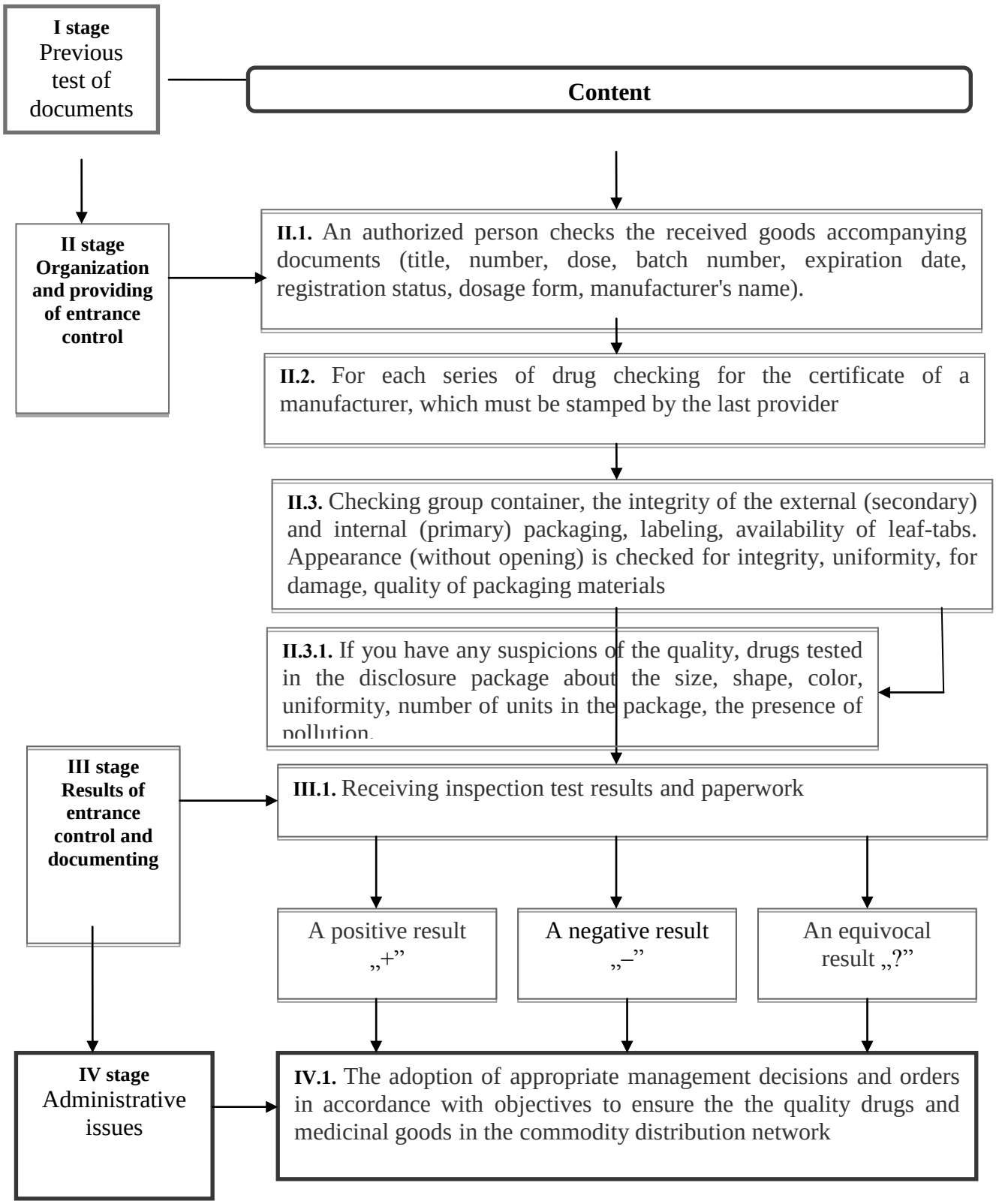
• granting territorial authority public service information identified substandard and counterfeit drugs or who is suspected of nonconformity to quality requirements;

• suspension of trading and placing in quarantine the area of drugs;

• coordination of internal order drugs trafficking.

The algorithm of the entrance control is shown at scheme 9.17. Before receiving the written opinion of the authorized person obtained drugs are prohibited.

More must be accompanied by a conclusion about the quality:
• substances used in pharmacies for the manufacture of parenteral dosage forms and drugs used in ophthalmic practice;
• narcotic drugs, psychotropic substances and precursors, which belong to the respective categories according to the list of narcotic drugs, psychotropic substances and precursors, and subject to special scrutiny under the law;
• drugs used for anesthesia, including inhalation (except for oxygen and nitrous oxide);
• radiopaque medicines;
• medicines (including combined) containing rifampicin, isoniazid, ethambutol, pirzynamid



Scheme. 9.17. The algorithm of entrance quality control of the drugs

Conclusion of the expert is the document with information about the tested model drugs, the results of laboratory research and opinion on compliance with operating in Ukraine, analytical and documentation. This document is issued by the accredited laboratory quality control of drugs, subordinate territorial office or an authorized laboratory.

With the positive result of the entrance control Authorized person notes the conclusion of the invoice with a resolution on the implementation of drugs (stamp "allows the realization of" date, signature). In the case of negative result is an act of returning the party drug supplier and immediately notified the territorial inspection. A copy of the act shall be submitted to the territorial inspection, if after further examination and sampling for laboratory analysis should take steps to inform other pharmacies to identify substandard, counterfeit, unregistered drugs and control of suppliers for destruction, disposal or return to manufacturer if faulty batches of drugs. In case of questionable results Inspector shall select samples of suspicious drugs and returned to the territorial inspectorate for passing laboratory. At the time of the laboratory, the final decision with regard to their quality, a series of questionable drug is in quarantine, isolation from other drugs marked "Trade is disabled till a head's order."

9.6. Organization of intrachemist's quality control of drugs

All production activities pharmacies should be aimed at providing high-quality manufacturing of drugs and providing quality, effective and safe medicines. The main tool for ensuring proper quality, compliance with the rules of manufacturing drugs with clearly organized intrachemist's control. Intrachemist's control - a set of preventive measures and control types that are made directly to the pharmacy and cover all stages of manufacturing drugs.

Responsibility for carrying out has pharmacist analytic. Head of Pharmacy, his deputies, Inspector shall also know all kinds of intrachemist's quality control and in the absence of pharmacist analytics to ensure their implementation.

In his office analyst pharmacist must:

• carry out all types of intrachemist's quality control according to the AND, technological instructions, etc.;

• ensure that the approved technical guidelines on the drugs that are produced commercially pharmacy;

• carry out systematic surveillance of the drug manufacturing process;

• refine the results already authorized person or conduct their own incoming quality control substances, herbal drugs and excipients;

• monitor the storage conditions and shelf life substances, excipients, concentrates, intermediate products, chemicals, titrate solutions;

• Ensure timely update titrate solutions and reagents, made on a contractual basis by accredited or certified laboratories;

• monitor compliance in pharmacy sanitary regime;

• remove the established order drug samples for the state quality control;

• regularly consult experts involved in the manufacture of drugs, for storage, technology and quality control of drugs;

• keep records of the form, make statements on the specified requirements.

Pharmacist-analyst has the rights to:

• prohibit (with simultaneous notification manager or his deputy) manufacture dosage forms under conditions that do not ensure their quality;

• withdraw from circulation made drugs, substances, excipients and concentrated and reagents if they fail AND, expiration or loss of registration status;

• prohibit the use of faulty, not attorneys instruments, measuring devices;

• send samples of treated water, water for injection, intravenous infusion, parenteral injection and other drugs for microbiological control to accredited or certified laboratories;

• make appropriate proposals to the organization of pharmacy in relation to quality assurance in the manufacture of drugs.

To ensure timely quality control of drugs and improve labor pharmacist analytics should be used Rigging and office equipment: titration for rapid analysis, plates with

indentations for the reaction of identification, a set of reagents and laboratory glassware for testing the purity of water and purified injection, a set of glasses for the control solution by burette installation; pipette Schuster for indicators and reagents; drawer-trays for papers, stationery. The presence of SPU, normative and technical documentation, internal technological instructions on drug-production, methods of analysis (from 01.01.2009, each of them must be validated), general and special reference books, normative acts to ensure, maintenance and quality control. Verification of measurement in accordance with the concluded contracts held metrological service.

Particular attention in the manufacture of drugs should be given to the preparation of water. This procedure is carried out in accordance with SPU to purified water and water for injection.

Intrachemist's control of drugs subject to all drugs made in pharmacies, solutions, concentrates, semi-purified water and water for injection, substances and excipients in filling in shtanhlas.

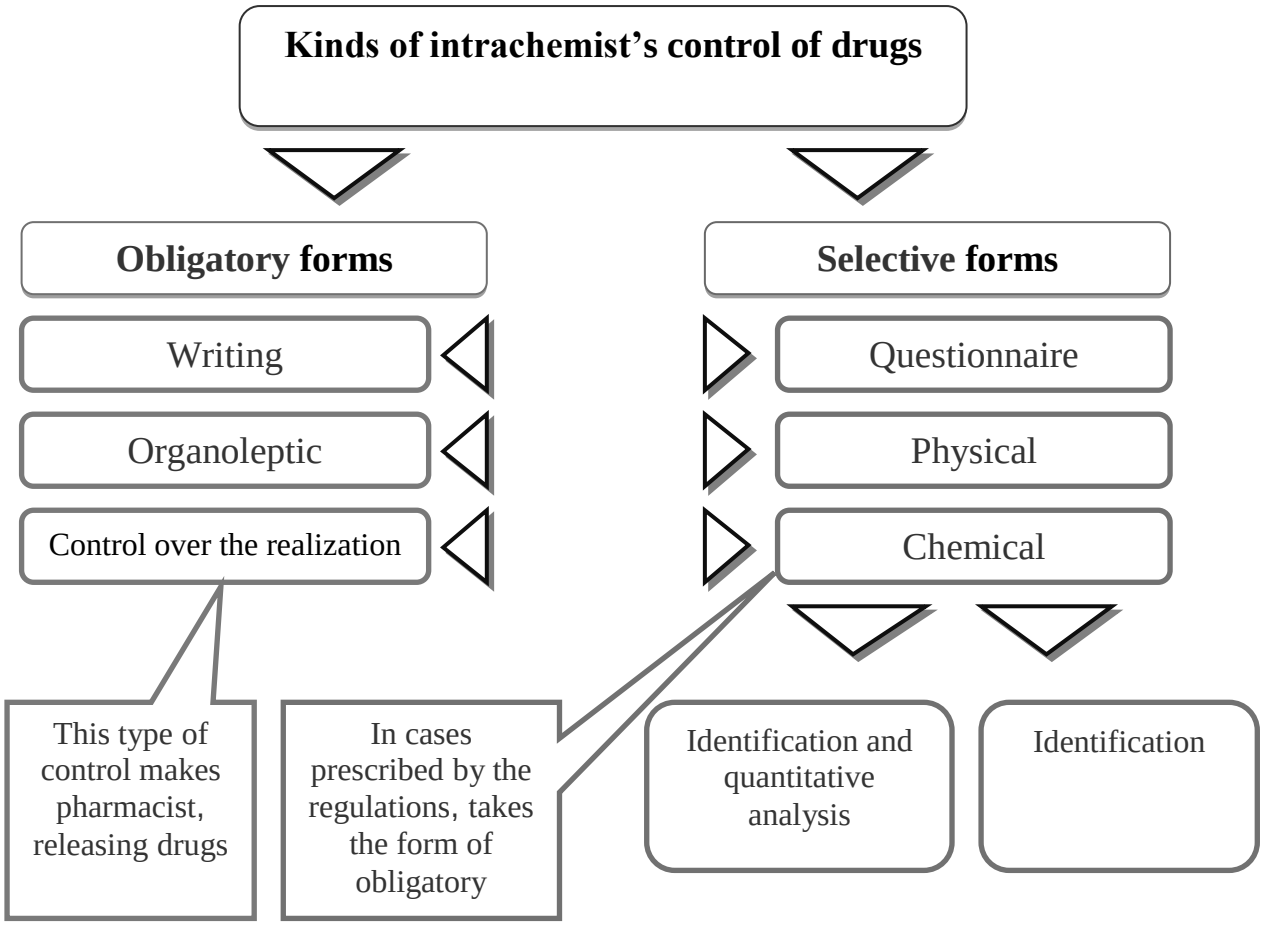
Under current law, there are six kinds of intrachemist's control of drugs: writing, questionnaire, organoleptic, physical, chemical control and monitoring during the leave. Conventionally, they can be divided into obligatory and selective (scheme 9.18).

The written control includes checking of the conformity of records in the passport of written control prescription in the recipe, correctness of the made calculations.

Organoleptical control is carried out as checking of appearance of the medicinal form, its color, smell, uniformity, absence of mechanical inclusions.

The control over sales 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.



Scheme 9.18. Classification of the kinds of intrachemists control of the drugs

Obligatory kinds are writing, organoleptic and control over the realization.

The *selective* forms of the control are:

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 other 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 can be «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 can be «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).

Specific requirements for inspection of water. Water purification and water for injection "in bulk" from each cylinder, and when presenting the pipeline on each job must withstand review in terms of "purity test".

9.7. Documentation of the results of the control of drugs made in pharmacies

Important role in ensuring the quality of manufactured drugs in the pharmacy is given the proper documentation of results intrachemists control. The results have to be recorded in journals by the form prescribed by the Ministry of Health of Ukraine. All logs should be on numbered pages, laced document, stamped and signed by the pharmacy manager / director.

Thus, the compounder of all drugs for individual prescriptions filles the passport of written control, which include: date, number of prescription (order), taken drugs and their quantity, number of doses, total weight or volume; signatures of persons are prepared, and packaging the drugs tested produced. Record in this passport must reflect the order of mixing ingredients and made in Latin from memory immediately after preparation. Using semi-finished and concentrates in the passport indicates their concentration, and the number of selected series. Be sure to specify the coefficients used in calculations: water absorption, increased volume and others. If the part of the dosage form are poisonous, narcotic and psychotropic substances and substances that are subject to quantitative control, the passport of written control completed only written on the back side of the prescription. Where a pharmacist analyst conducts physical and chemical control, in addition to the passport number tabulated analysis and signature pharmacist analytics. Signed passport of written control have to be stored in the pharmacy for two months. Concentrates, intermediate products and packing of drugs are to be recorded in the Journal of laboratory and packing operations. Results of organoleptic, physical and chemical control have to be recorded to the Journal of the results of control of drugs manufactured in the pharmacy and ethanol. With a large amount of work on this form is allowed to separate logs from specific, for example, separately for the ready-made drugs and for individual drugs or prescription requirements.

Conclusion denoted by "satisfactory" or "unsatisfactory." To determine the nature of doubtful of drugs are established such differentiations:

1. Poor for identification:

• no prescribed ingredient;

• availability of a component is registered;

• use of drugs-related analogs without your doctor in the recipe.

2. Poor physical performance by:

• improper mixing or grinding the ingredients;

• contamination of solution contamination;

• exceeding the standards deviation of individual doses, the total mass (volume);

• improper or vidvazhuvannya measuring individual ingredients.

Solutions for injection are rejected by their inconsistency of physical and chemical parameters, presence of visible mechanical inclusions, violating fix package (checking tightness of sealing scrolls aluminum cap), lack of volume filling bottles.

Unsatisfactory results have to be underline in red pencil. In the same journal record all cases of faulty manufacture drugs. Then all substandard medicines on the basis of the decision of the authorized person shall be seized in quarantine, recycled or destroyed in accordance with legislation.

"Testing for purity" water used for manufacturing drugs pharmacy, documented drawn in two different journals: log monitoring results of water and purified water for injection "in bulk" and log the results of monitoring sterile water for injection. The absence of impurities in the corresponding graphs indicates the sign "-", that is within the standard. Particular attention should be paid to documenting of bunch manufacturing of drugs in the pharmacy. In this case, a series of drugs - a certain number of homogeneous products (drugs), made in pharmacies with a number of raw materials in a single technological process of a capacitive load per unit of equipment. Each batch of drug produced in accordance with technological instruction.

Technology Instruction - an internal document of the entity that falls under the category of manufacturing instructions, indicating technological methods, means, norms and standards for the manufacture of drugs, methods of control with the

establishment of quality and quantity of drugs, their limits, requirements for packaging labeling, storage conditions, shelf life.

For parenteral, ophthalmic and other drugs that are produced in series and which is required regarding their sterility, quality control should cover all stages of manufacturing the drug. Under these conditions, to process instruction additionally make a list of activities carried out by stepwise control. Results of stepwise control are entered in the "log of individual stages of production of injection, intravenous and ophthalmic drugs." In this form, you can record data during the day on a separate sheet, but of mandatory binding. Results of monitoring of these drugs as finished products are registered in the relevant journal, features which are still required

Under current legislation, to identify substandard drugs and prevent similar occurrences pharmacy must ensure consideration of claims made and sold drugs, and systematization of reported adverse reactions and side effects of drugs of outpatient patients and health care facilities. Special registration forms will not be given. Therefore, documenting this information should be in any order by developed over the counter form.

If there are gross violations and, consequently, have any doubt about the quality of a drug produced in the pharmacy, the state inspector selects samples of such drugs to control in an accredited laboratory.

References

1. Azhar Yaqoob Khan[1], Naushad M. Khan Ghilzai Counterfeit and substandard quality of drugs: The need for an effective and stringent regulatory control in India and other developing countries http://www.ijp-online.com/article.asp?issn=0253-7613;year=2007;volume=39;issue=4;spage=206;epage=207;aulast=Khan
2. Guidelines on the implementation of the WHO certification scheme on the quality of pharmaceutical products moving in international commerce http://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/guidelines/en/index1.html
3. Model certificate of a pharmaceutical product http://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/modelcertificate/en/

Review questions

1. Give a definition of "quality drugs", " counterfeit drug", "defective / substandard drug" and "unregistered agent" under the editorship of WHO.

2. Describe the form of quality assurance of drugs in the WHO Certification System.

3. What information does the certificate (passport) of a producer include?

4. Provide organizational structure of the System. Which structures and organs are presented in the first, second and third level?

5. List the rights and obligations of the pharmacist analytics.

6. What kinds of intrachemist's quality control of drugs you know?

7. What drugs are subject to obligatory chemical control?

Check Your Understanding

1. The main components of the model systems in accordance with international guidelines and standards should include:
   a) Developed infrastructure pharmaceutical market
   b) Service Inspectorate
   c) Availability of analytical laboratories with the necessary financial, personnel, regulatory, technical and information support
   d) Private sector in the structure of the pharmaceutical industry
   e) The administrative unit with clearly defined rights and duties of employees who provide quality control of drugs.
2. The following information is present in the certificate (passport) of a producer:
   a) A series of drugs
   b) Characteristics of drug production in the enterprise
   c) International and trade name drugs
   d) Number of registration certificate and shelf-life of drugs
   e) Results of inspections of drugs

3. Match the term with its contents:

	Term		Content
A	counterfeit drug	1	Drug that deliberately marked nonidentical (not in) information (one or more of them) of drugs with the appropriate name included in the State Register of Ukraine drugs, as well as drugs, deliberately forged in a different way, and does not correspond to the information (one or more of them), including composition of drugs with the appropriate name included in the State Register of Ukraine drugs
B	defective / substandard drug	2	Drug that made by a legal manufacturer with the correct labels, but that during production, transportation, storage lost compliance with the approved analytical documentation.
C	unregistered drug	3	Drug that did not pass the procedure of state registration with the relevant authorities and not included in the State Register of drugs.

4. The current system of the medicine quality control performs the following functions:

   a) Regulated

   b) Accounting

   c) Stimulating

   d) Controlling

   e) Managerial coordination

5. National Expert Center in the structure of the System performs the following functions:

   a) Expert

   b) Regulated

   c) Research

   d) Advisory

   e) Production

6. The duties of the Inspector include:

   a) Obtain a written explanation of the issues that arise during inspections

   b) Objectively and fully reflect the situation regarding compliance to ensure quality drugs.

   c) Ensure confidentiality while verify the information.

   d) Without prejudice to review of any premises.

   e) Ban advertising of OTC drugs on the trading floor pharmacy

Chapter 10. ORGANIZATION OF MEDICINE PROVIDING IN PHARMACY

Pharmaceutical providing 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.

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.

To organize the effective medicine procurement and providing one can use the international standards of the good pharmaceutical procurement practice.

10.1. 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. It pays attention a brief problem statement which illustrates the need for improvements in procurement practices.

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.

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 procurementis shown at scheme 10.1.

Scheme 10.1. GPPP strategic objectives

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.

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

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.

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.

10.2. Operational principles for good pharmaceutical procurement Efficient and Transparent Management

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.

Procurement procedures should be transparent, following formal written procedures throughout the process and using explicit criteria to award contracts.

Procurement should be planned properly and procurement performance should be monitored regularly; monitoring should include an annual external audit.

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.

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 tenderparticipation; 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.

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.

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.

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.

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

There are four main methods for purchasing drugs. Three of them are competitive: restricted tenders, open tenders and competitive negotiations. Thefourth 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.

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

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

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

10.3. Organization of medicine supply system in pharmacy

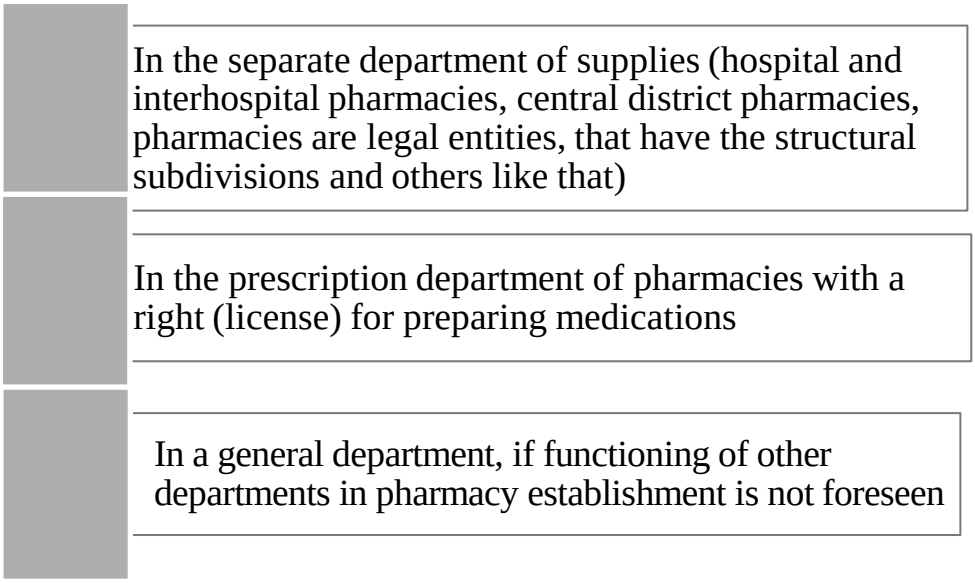
The level of provision of health facilities with safe, effective, quality medicines and medical products, their availability and rational use largely depends on the commodity stocks (supply) of pharmacies.

Commodity stocks are a quantity of drugs and medical devices and other pharmaceutical products assortment, which is in circulation and is subject to sales.

The commodity stocks include:

- Products that are available in pharmacies and its structural subdivisions (pharmacy points);
- Products that are purchased and left for responsible storage at suppliers;
- Products that are were put for recycling (ex. medicinal herbs)

Depending on the structure of pharmacy, the types of its activities (retail, wholesale sales, with the right to manufacture drugs, etc.) commodity stocks can be concentrated in different places (scheme 10.2).



Scheme 10.2. Placement of commodity supplies

Commodity stocks are an important indicator of product coverage sales. In total current assets and pharmacy commodity stocks occupy the main place, and their share is 75-80%.

Commodity stocks can be increased due to the transfer of other inventory items at product (packaging, medicinal plant raw materials etc.).

A commodity stock are measured generally in monetary terms and consists of the total value of certain commodity positions total pharmaceutical product range, as well as in days - mean number of days for which the stock is sold. Some commodity items can also be measured in physical terms (units, kg, m, etc.).

Determining the need for medicines and pharmaceutical goods assortment.

To compile the application for optimal assortment of pharmaceutical products at first must be correctly identify the need in medicines. Determination of the need for pharmaceutical goods assortment administer pharmacy departments, managers and based on a systematic analysis of the dynamics of assortment of pharmaceutical products.

Orders of pharmacies should contain only products that are entitled to buy and sell by pharmacies according to the order of Ministry of Health care of Ukraine.

During drawing up standard contracts preferably guided GPPP (Good pharmaceutical procurement practice), which regulates the procurement of drugs for the public health sector at national and regional levels and can be used by any organizations and institutions engaged the purchase of drugs.

10.4. 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 organized 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 100 000, 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 ot 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 NYJOO17
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).
4. Certificate of quality.
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 shell 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 Buyer

xxxx

252000 KIEV, UKRAINE
61 ,Tupikovaya Str.
Tel: (044) 000-00-00,
Fax: (044) 000-00-00
ac.0000000000 ,Ukreximbank of Kiev MFO 000000, ZKPO of bank 00000000

The Seller
PFIZER H. C. P. CORPORATION
432-4408232-16
235 East 42nd Street
New York NY 10017
c/o Central & Eastern Europe Region
Hoge Wei 10
B-1930 Zaventem, Belgium
held with KREDIETBANK Brabant West Corporate
Rue de Ia Technologie 1,
1082 BRUXELLES
Belgium
SWIFT: KREDBEBB
Fax n: 02/469-01-22

10.5. The most popular terms of deliveries according to the international rules INCOTERMS

"Incoterms" are the official International Chamber of Commerce (ICC) rules for the interpretation of international trade terms that defines the respective roles of the buyer and seller in the arrangement of transportation and other responsibilities and clarify when the ownership of the goods takes place.

Incoterms are international rules that are accepted by governments, legal authorities and practitioners worldwide for the interpretation of the most commonly used terms in international trade. They either reduce or remove altogether uncertainties arising from differing interpretations of such terms in different countries.

"Incoterm" are the official International Chamber of Commerce (ICC) rules for the interpretation of international trade terms that defines the respective roles of the buyer and seller in the arrangement of transportation and other responsibilities and clarify when the ownership of the goods takes place.

The purpose of *Incoterms* is to provide a set of international rules for the interpretation of the most commonly used trade terms in foreign trade. Thus, the uncertainties of different interpretations of such terms in different countries can be avoided or at least reduced to a considerable degree.

In 2010 the ICC developed the new version of Incoterms. Moreover, changes were made to both the structure and the contents of the rules. This version entered into force on 1 January 2011.

New classification of Incoterms conditions in Incoterms 2010 the number of terms has been reduced to 11, and they are combined into two groups:

1. Terms used for shipment via any forms of transport

- EXW Ex Works
- FCA Free Carrier
- CPT Carriage paid to
- CIP Carriage and Insurance paid to
- DAT Delivered at Terminal

■ DAP Delivered at Place

■ DDP Delivered Duty paid

These terms can be used regardless of the chosen form of transport. They are also applicable if maritime transport is not used at all, or in the case of delivery of freight by several means of transport with partial conveyance via a waterway.

2. Terms used for maritime and internal waterway transport

■ FAS Free alongside Ship

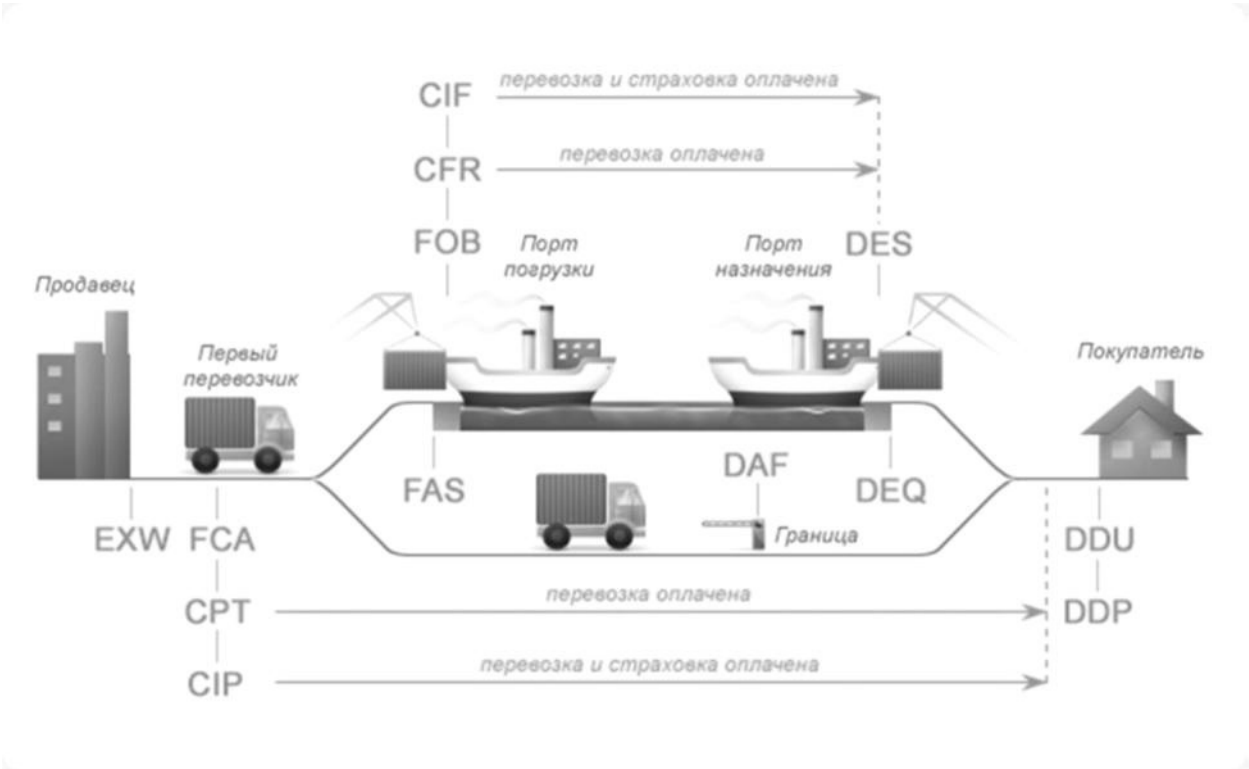
■ FOB Free on Board

■ CFR Cost and Freight

■ CIF Cost, Insurance and Freight (scheme 10.3)

In the terms FOB, CFR and CIF mention of a ship's rail as the point of delivery has been excluded, since the notion of "passage over ship's rail" defined the place of delivery relatively loosely.

In accordance with the terms FOB, CFR and CIF in Incoterms 2010, goods are considered delivered when they are "on board" the ship.



Scheme 10.3. Terms of Incoterms

Along with the introduction of the new classification, the Incoterms conditions have been divided into two groups, depending on the moment of delivery:

Shipping terms are conditions pursuant to which a delivery is carried out until the moment of transfer of the goods. Thus, all risks connected with transport are generally imposed upon the buyer, although in certain cases the seller can also assume corresponding expenses. This group includes the conditions of group ”E”, ”F” and ”C”.

Delivery terms are provisions determining the transport conditions until the moment of delivery of the goods. In such case, all risks arising during transport are born by the seller. This group includes all terms of group ”D”.

Main innovations of Incoterms 2010

One of the substantial innovations in Incoterms 2010 is that these terms may be applied not only in international trade, but in domestic trade as well. For example, they may be used in an agreement entered into between two Russian companies. Apart from everything else, two new terms were introduced into Incoterms 2010 (see below for more details):

DAT (Delivered at Terminal), replaces the previous term DEQ (Delivered Ex Quay), used in Incoterms 2000;

DAP (Delivered at Place), replaces the previous terms DAF (Delivered at Frontier), DES (Delivered Ex Ship) and DDU (Delivered Duty Unpaid), used in Incoterms 2000.

Incoterms 2010 establish that for designating the choice of applicable conditions an agreement must use the addition ”Incoterms 2010”, for example: ”Ex Works Incoterms 2010”.

Incoterms 2010 take into account the particular features of trade in commodities, which undergo repeated sales during transport (so-called string sales). For this purpose, the rules of Incoterms have been supplemented with an obligation regarding «provision of shipped goods” as an alternative to shipment of goods.

The terms DAT and DAP

According to these new terms, a delivery is carried out at an agreed destination:

1. DAT Delivered at Terminal (with specification of the port terminal or destination) Incoterms 2010 pursuant to **DAT**, at the terminal goods are placed at the buyer's disposal, unloaded from the arriving vehicle (previously in such situations the term **DEQ** (Delivered Ex Quay) was used). This term may be used regardless of the chosen type of transport, as well as when several types of transport are used. The seller carries out the delivery when the goods, unloaded from the arriving vehicle, are placed at the buyer's disposal at the agreed terminal at the named port or destination. The seller bears all expenses prior to the moment of transfer of the goods to the buyer, including expenses for loading the goods, shipping them to the terminal and further unloading. The seller is also responsible for performing the customs formalities required for exporting the goods, if applicable. At the same time, the seller is not obligated to provide for customs clearance and pay import duties during the import of the goods. Generally, the risks of loss of or damage to goods until the moment of delivery lie with the seller. As of the transfer of the delivery they pass to the buyer. It is possible to pass the risks to the buyer earlier if the buyer does not perform its obligations to obtain required licenses and fulfill customs formalities for importing the goods, or if it does not notify the seller of the specific date or place of acceptance of the delivered goods, provided that the goods were individualized.

2. DAP (with specification of the destination) Incoterms 2010 Pursuant to **DAP**, goods are transferred to the buyer in a form ready for unloading at the agreed place (previously this condition was regulated by the terms **DAF** (Deliver at Frontier), **DES** (Delivered Ex Ship) and **DDU** (Delivered Duty Unpaid)). This term may be used regardless of the chosen type of transport, as well as when several types of transport are used. According to this term, the seller carries out the delivery when the goods ready for unloading are placed at the buyer's disposal on the arriving vehicle at the agreed destination on the agreed date or within the agreed period. The

seller bears the expenses associated with loading and shipping the goods to the destination. Furthermore, the seller is responsible for fulfilling the customs formalities necessary for exporting the goods, if applicable. At the same time, the seller is not obligated to provide for customs clearance and pay import duties during the import of the goods. Generally, the buyer bears the expenses connected with unloading the goods. However, a shipping agreement may assign these expenses as an obligation of the seller. If under shipping agreements the seller bears expenses for unloading at the agreed destination, it is not entitled to demand that the buyer reimburse the expenses, unless the parties agree otherwise. Generally, the risks of loss of or damage to goods until the moment of delivery lie with the seller. As of the delivery the risks pass to the buyer. However, in certain cases the risks pass to the seller earlier than as foreseen by the term **DAT**. Parties are recommended to precisely agree upon the place at the destination, as the seller bears risks until the freight arrives at such place. It is recommended that the seller provide for shipping contracts that clearly reflect the choice of this place. Freight insurance Similar to Incoterms 2000, the Incoterms 2010 version mentions freight insurance only twice – in the terms **CIF** and **CIP**.

As regards division of obligations concerning freight insurance, Incoterms 2010 takes into account the change in the so-called Institute Cargo Clauses (freight insurance terms adopted by the Institute of London Underwriters). In accordance with the terms **CIP** and **CIF** the seller is obligated to insure the freight at its own expense, where the insurance must provide for the minimum coverage stipulated in clause **"C"** of the freight insurance terms adopted by the Institute of London Underwriters or other similar rules. Thus, the insurance must at a minimum cover the price specified in the contract plus 10% (i.e. 110%). The insurance must cover risks associated with the goods from the start of transport to arrival at the established destination.

At the buyer's request and at its expense, the seller shall enter into an additional freight insurance agreement, as specified in clauses **"A"** or **"B"** of the

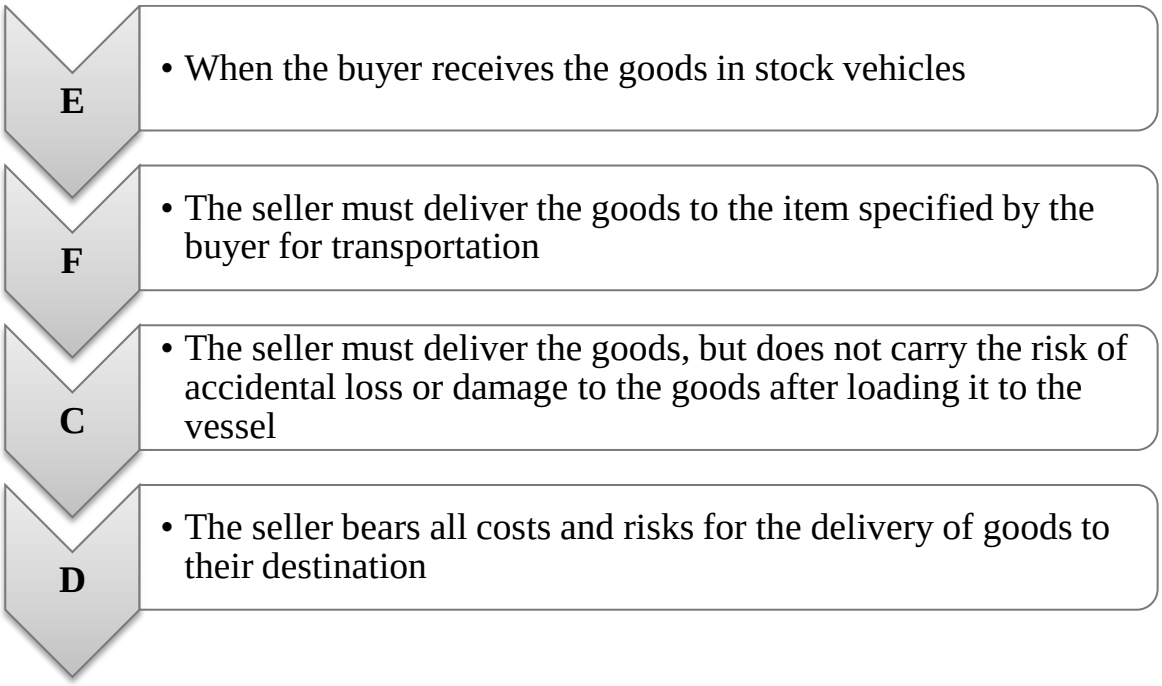
freight insurance terms adopted by the Institute of London Underwriters. It must guarantee more complete insurance of the freight.

Clauses **”A”**, **”B”** and **”C”** of the freight insurance terms adopted by the Institute of London Underwriters stipulate exclusions from the scope of insurance coverage, for example in the event of damage caused as a result of acts of war, strikes, civil unrest, etc. Such risks need to be additionally insured.

When choosing the type and scope of freight insurance the buyer must analyze the risks threatening the freight during transport. To a certain degree it is worth proceeding from the premise that during the shipment of finished manufactured goods there is a relatively high probability of theft or improper storage. Due to this, one should enter into a freight insurance agreement in accordance with clause **”A”** of the freight insurance terms adopted by the Institute of London Underwriters. For raw materials not exposed to particular external stress, it is sufficient to enter into a common insurance agreement in accordance with clauses **”B”** or **”C”** of the freight insurance terms adopted by the Institute of London Underwriters.

Since the other terms of Incoterms 2010 do not stipulate freight insurance, parties often forgo it. They hold the opinion that the risk of damage or loss is sufficiently covered by the insurance of the freight carrier. However, in practice difficulties sometimes arise when asserting claims against a carrier in connection with losses, as the scope of liability of a freight forwarder is often limited by national laws or international agreements. In this regard, parties to a sale and purchase agreement may be recommended to divide obligations regarding insurance also in the context of other terms of Incoterms 2010, since in the case of insuring freight, in contrast to insuring civil liability, the very fact of damage or loss entitles the owner to claim for reimbursement of the losses from the insurance company. Moreover, the owner is not obligated to prove the cause and effect relationship between actions of the forwarder and the damage to or loss of the freight.

The basic terms "Incoterms" (13 of them) combined into four groups (scheme 10.4).



Scheme 10.4. Four groups of terms of Incoterms

The concept of "free" (Franco) which is used for the designation of the basic conditions means that the buyer is free from risks and all the costs of delivery of the goods to the point specified by the word "free" Ex Works (EXW) means that the seller's obligation to deliver shall be considered fulfilled after he gave the goods in a company (factories, warehouses, etc.).

"E" - is the term in which the seller's obligation is at its minimum: seller has to do no more than place the goods at the disposal of the buyer at the agreed place - usually at the seller's own premises. On the other hand, as a matter of practical reality, the seller would frequently assist the buyer in loading the goods on the latter's collecting vehicle. Although EXW would better reflect this if the seller's obligations were to be extended so as to include loading, it was thought desirable to retain the traditional principle of the seller's minimum obligation under EXW so that it could be used for cases where the seller does not wish to assume any obligation whatsoever with respect to the loading of the goods.

"F" - terms require the seller to deliver the goods for carriage as instructed by the buyer. The point at which the parties intend delivery to occur in the FCA term has caused difficulty because of the wide variety of circumstances which may surround

contracts covered by this term. Thus, the goods may be loaded on a collecting vehicle sent by the buyer to pick them up at the seller's premises; alternatively, the goods may need to be unloaded from a vehicle sent by the seller to deliver the goods at a terminal named by the buyer.

"C" -terms require the seller to contract for carriage on usual terms at his own expense. Therefore, a point up to which he would have to pay transport costs must necessarily be indicated after the respective «C»-term. Under the CIF and CIP terms the seller also has to take out insurance and bear the insurance cost. Since the point for the division of costs is fixed at a point in the country of destination, the «C»-terms are frequently mistakenly believed to be arrival contracts, in which the seller would bear all risks and costs until the goods have actually arrived at the agreed point. However, it must be stressed that the «C»-terms are of the same nature as the «F»-terms in that the seller fulfills the contract in the country of shipment or dispatch. Thus, the contracts of sale under the «C»-terms, like the contracts under the «F»-terms, fall within the category of shipment contracts.

The essential nature of the "C" - terms as shipment contracts is also illustrated by the common use of documentary credits as the preferred mode of payment used in such terms. Where it is agreed by the parties to the sale contract that the seller will be paid by presenting the agreed shipping documents to a bank under a documentary credit, it would be quite contrary to the central purpose of the documentary credit for the seller to bear further risks and costs after the moment when payment had been made under documentary credits or otherwise upon shipment and dispatch of the goods.

«D» - terms are different in nature from the «C»-terms, since the seller according to the «D»-terms is responsible for the arrival of the goods at the agreed place or point of destination at the border or within the country of import. The seller must bear all risks and costs in bringing the goods thereto. Hence, the «D»-terms signify arrival contracts, while the «C»-terms evidence departure (shipment) contracts.

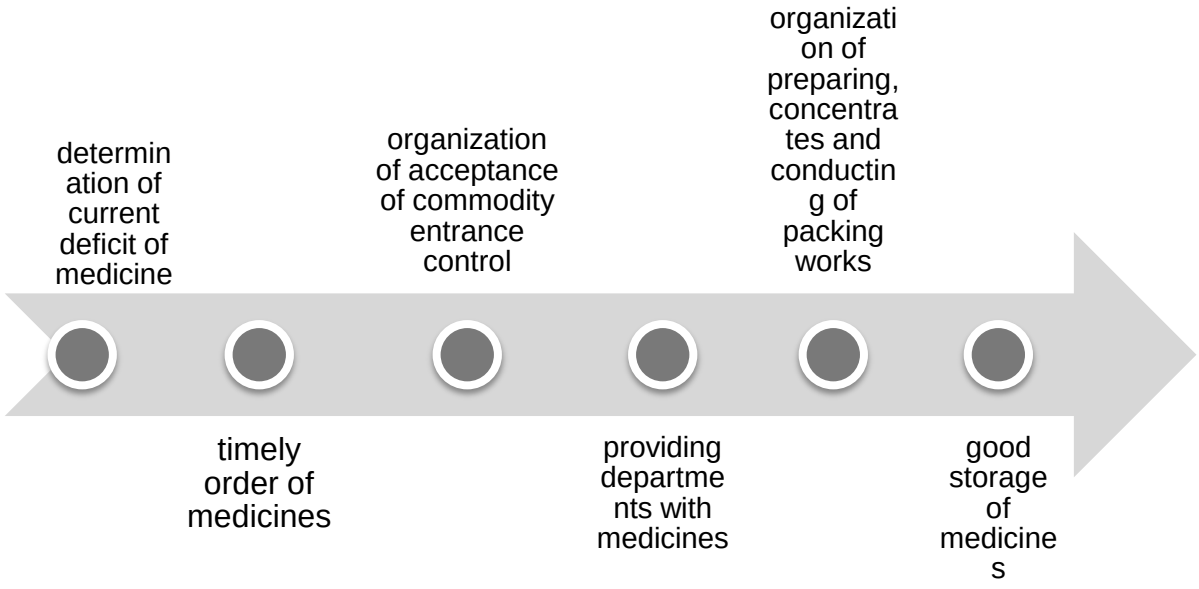
Under the «D»-terms except DDP the seller does not have to deliver the goods cleared for import in the country of destination.

It appears that in many countries trade terms not included in Incoterms are used particularly in railway traffic («franco border», «franco-frontiere», «Frei Grenze»). However, under such terms it is normally not intended that the seller should assume the risk of loss of or damage to goods during the transport up to the border. It would be preferable in these circumstances to use CPT indicating the border. If, on the other hand, the parties intend that the seller should bear the risk during the transport DAF indicating the border would be appropriate.

As has always been underlined by ICC, Incoterms deal only with the relation between sellers and buyers under the contract of sale, and, moreover, only do so in some very distinct respects.

10.6. The organization of storage department in the pharmacy

The storage department and its pharmaceutical personnel, who are responsible for addition to the commodity supplies and their storage, carry out several functions (scheme 10.5).



Scheme 10.5. Responsibilities of storage department and its stuff

To perform these functions storage department should have the ***following areas:***

- Room (zone) for storage of drugs, herbal drugs, bandaging materials, auxiliary materials, packaging, etc;

- Room for servicing healthcare facilities;
- Room for laboratory and packing operations;
- Room maintenance healthcare facilities (for receiving and processing orders);
- Room for laboratory and packing operations (preparation of concentrates, intermediate products, intra workpieces).

Workplaces should be equipped by small mechanization: weight for packaging liquids, devices for dosing and packaging of powders, caps on bottles, devices for filtering solutions, grinding and mixing of powders, magnetic mixers etc.

Staff of the department includes: Head of department, his deputies, pharmacists technologists, packers and others.

Duties of the Head of Department and its assistances:

- Compliance of pharmaceutical, sanitary and epidemiological regime in the department;
- Ensuring the availability of the department required range of goods;
- Proper storage and dispensing of drugs, medical devices and pharmaceutical products;
- Timely compilation of orders to the supplier;
- Acceptance of products from suppliers and verification of quantitative and qualitative characteristics;
- Supply of goods to other departments, its structural subdivisions and other organizations;
- Traffic account of goods and drafting reports;
- Organizing the laboratory- packing operations;
- Briefing staff about the procedures of the department, review of legislative acts, regulations, instructions.

Duties of pharmacist - technologist:

- Conducting laboratory and packing operations (manufacturing concentrates , intermediate products) and documented;
- Control the substances in the assistant room (presence of number series factory, company, expiration date , № analysis , the date of completion);

- Enforcement storage of drugs, medical devices and other pharmaceutical products;
- Distribution of work between the packers, receiving from them the finished product, proper documentation of packing operations;
- Participation in the acceptance of the goods and their proper placement in the material room;
- Making of orders for other departments stores and other client organizations.

Department of supplies may carry out laboratory and packing work. This work is carried out with the right on drugs manufacturing, including aseptic conditions (for this drug should be separate areas: aseptic bloc, sterilization, facilities for water for injection, pharmacist analyst).

Acceptance of commodity from a supplier (factory-producer, wholesale firm and others like that) in pharmacy establishment have to be carried out by an **authorized person** that is appointed by the order of the manager.

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 there is a notebook for "entrance control", in which is fixed: record, date of receipt of commodity, series and amount, name of supplier, who accepted and who checked up a commodity.

For the medicines in "angro" there is additional analysis on accordance by the high-quality reactions, and fixed in the special journal.

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 with all requirements of operating normatively-technical document. They must be provided with protective and fire-prevention facilities.

Proper conditions for storage areas:

Each drug storage area shall be maintained in a clean and orderly condition. 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 so the apartments must be equipped by thermometers and hygrometers. Refrigeration storage equipment used capacity exclusively for drugs.

Drugs in the storage area shall be accurately labeled. Until a drug is administered or dispensed, it shall be kept in the manufacturer's original container showing the manufacturer's lot number and the expiration date. Drugs in the storage area shall be free from adulteration. Appropriate procedures shall be established to minimize the hazards of cross contamination.

All drugs shall, at all times, be stored at a temperature which complies with the standards established by the current volume of the Pharmacopeia. Performance of requirements of this instruction is obligatory for all pharmacy establishments, regardless of their submission and patterns of ownership.Placing drugs and medical devices should be on the shelves, in closets, and if necessary - on special pallets on the floor. To avoid errors when using is not recommended placing next to tune by name drugs, drugs for internal use which differ significantly higher doses.

In Ukrainian practice is considered inappropriate location of drugs in alphabetical order, although this is in the pharmacies and wholesalers of pharmaceutical companies especially some well-known countries for ease of automated search of drugs and medical devices.

Basic principles of storage of drugs and medical devices:

- In accordance with toxicological groups: poisonous and narcotic matters; drastic matters and general medicines.
- In accordance with pharmacological groups;
- Depending on the method of the use (internal, external);
- Medicines in "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;
- Subject to set expiration dates of drugs;
- Taking into account a character of different medical forms;
- Medical products should be stored separately in groups: rubber wares, wares from plastics, bandaging and auxiliary materials, and wares of medical technique.

10.7. Good Storage Practice as an element of the high quality providing

Storage of drugs and medical devices is desirable to perform in accordance with **Good Storage Practices (GSP)**, which is designed for all employees relating to the storage, transportation and distribution of pharmaceutical products. GSP is closely related to other types of good practices: GMP, GDP, etc., describes the specific actions necessary for the proper storage and transportation of pharmaceutical products and can be used by manufacturers, importers, suppliers, pharmaceutical products, pharmacies, medical services providers. GSP governs the staff requirements specified institutions, organizations, facilities, records and information, containers and sampling of goods, transport and withdrawal of products.

Manual on Good practice of storage of pharmaceutical production

The given manual is intended for all workers concerning storage, transportation and distribution of pharmaceutical production. It includes the information about the personnel, conditions of the storage and the room and the equipment, how to held the control and accounting of the process accompaing the practice of storage of pharmaceutical production. Shortly on this question you can find the information below.

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

The personnel

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.

The personnel should pass training to appropriate practice of storage, the legislation, procedures and security measures.

A room and the equipment

Room for storage of production

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

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.

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 places for cleaning and survey. Pallets should be in good condition and clean.

The room for storage of production should be clean, it is impossible to suppose congestions of dust or occurrence of wreckers and parasites. Means for disinfection and deracination should be safe.

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.

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.

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

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

The damaged products should be withdrawn and placed separately.

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

Conditions of storage

Conditions of storage of pharmaceutical products and materials should correspond to requirements of a label, based on results of researches of stability.

The control over conditions of storage

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.

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

Requirements on storage of production

The documentation: written instructions and reports

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 moving materials, pharmaceutical products and information

within the limits of the organization on a case of occurrence of necessity of a response of a product.

Marks and containers

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.

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

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.

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.

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.

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

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

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

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

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

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

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.

A response of production

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 to 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.

10.8. Terms of storage various groups of drugs and medical devices, depending on the physical and physico-chemical properties and actions of various environmental factors.

Drugs that require protection from light (antibiotics, Galen drugs, vitamins, corticosteroids, essential and fatty oils, etc.) should be stored in containers with dimming materials: glass containers orange glass, metal and plastic containers, colored black, brown or orange in a dark room or closet, painted inside with black paint, completely protected from light. *Sensitive to light drugs* are stored in a glass container that covered with black paper.

The opposite storage conditions apply to *drugs* that, by contrast, *need the light* (preparations of iron oxide): a small glass container on the most affordable places to sunlight.

Drugs that require protection from moisture (antibiotics, glycosides, enzymes etc.) should be stored in a cool place in a tightly packed container of materials that impenetrable to water vapor (glass, metal, aluminum foil, thick-walled plastic container). Among this distinguished group of drugs identified *hygroscopic properties* (chlorpromazine, barbamyl, glucose, dibazol, diphenhydramine hydrochloride, potassium iodide, sodium bromide, pepsin, protargol, thick extracts, etc.) that can be stored in a dry place in a glass container with a tight blockage, pour on top paraffin.

For *drugs that require protection from weathering* (evaporation) should be stored in a cool place in a tightly sealed container with opaque material for volatile substances (glass, metal, aluminum foil).

Storage of *drugs that require protection from the effects of high temperature* (bacterial, hormonal, vitamin, antibiotics, medical, fats and oils, etc.) performed at a room temperature (18-20 °C), cool (12-15 °C).

Storage of *odorous, coloring and disinfectants* should be separately in a tightly closed container, impervious to odors, apart from names. in an isolated room, away from the premises for the storage of plastic, rubber and metal products, facilities for obtaining purified water.

Herbal drugs must be stored in a dry, well-ventilated area in a clean, dry, without any odors container at the optimum temperature (18-200 °C) and humidity - 30-40%.

Dressing's products should be stored in a dry ventilated area in closets, drawers, on shelves and pallets that should be colored in bright oil paint and kept clean.

Special storage conditions require *flammable and explosive medicines* and medical products. *Flammable and inflammable substances* must be stored separately from other materials away from heat, in tightly sealed containers. *Explosives and explosive substances* must be stored in special fireproof insulated rooms (compartments) with refractory walls.

Poisonous drugs, regardless of the dosage form should be stored in locked metal cabinets that are isolated material room with bars on the windows.

Controlled substances shall be stored in a substantially constructed, locked in a container such as a cabinet or safe. All prescription drugs shall be stored in an area which is under the immediate control

Vaccines should be stored in an area away from refrigerated/frozen medications and protected from light.

Persons who 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 journal.

It is recommended to use the following formulations of instructions on labels:

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

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Supply of goods to departments' of pharmacies and its own retail network is doing by their requests, invoices accompanied by internal displacement.

For products from the pharmacy (from the storage department) health care facilities requirements, prepares invoices in 3 copies, the first of which is transmitted along with the trade report to the accounting pharmacy, along with other bills to pay - to the customer accounts, the third - the recipient of the goods. These requirements-certified overhead corner stamp institution, signed by the head of health care facilities (Research Institute), during his absence – by his assistant.

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Review questions

1. What documents is processed at delivery of commodity in the departments of pharmacy?

2. Characterize the concept of the Good pharmaceutical procurement and Good Storage practice.

3. What are the rules of storage of poisonous substances (including especially poisonous), narcotic substances and preparations equated to them?

4. Call the requirements and terms of storage of medications depending on their physical and chemical properties and influencing of external factors.]

5. What the international rules Incoterms do you know?

Check Your Understanding

1. The wholesale firm realized medicines to the pharmacy: Vikair tabl. № 10, Vinpocetin tabl. 5 mg № 30. Indicate their minimum remaining term of storage.

A No less than 60 %

B No less than 80 %

C No less than 70 %

D No less than 50 %

E No less than 40 %

2. Medicines are entered the pharmacy. What from the given medicines must be kept in the separate room in the closed container?

A Methylsalicylate

B Magnesium oxide

C Ethazol sodium

D Calcium phosphate

E Sodium of para-aminosalicylate

3. Define, what department of pharmacy is engaged in the reception of commodity on quantity and quality, in storage and supplying to other departments of pharmacy:

A Department of storage

B Prescription department

C Ready-made drugs department

D Non-Prescription department

4. Commodity turnover (sales) is one of economic parameter of pharmacies activity. By the basic document, which determines the rights and duties of parties on delivery of all types of commodities of pharmacy assortment, is:

A Contract

B Certificate of writing

C Quality certificate of commodity

D Tax invoice

E Certificate of selection of samples

GLOSSARY

A

Authorized person

is a person the proper performance of duties which guarantees the quality of drugs and medicinal goods coming to the entities.

C

Certificate of analyses

is a document certifying compliance of information, given in the specifications of the drugs that provided by the manufacturer of drugs; issued by the State Service of drugs.

Certificate of quality

is a document certifying the quality of drugs issued by the manufacturer for each series of drugs.

Certification

is a set of measures during which the third (independent party) give a written guarantee that the product, process or service meets the approved requirements. World Health Assembly at the 50th session in 1996, urged all countries to use the Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.

Commodity stocks

are a quantity of drugs and medical devices and other pharmaceutical products assortment, which is in circulation and is subject to realization.

Counterfeit medicine

is a pharmaceutical product gives a false representation of its identity and/or source and/or record keeping for traceability; pretends to have been assessed and approved by the competent regulatory authority, pretending to be a genuine quality product; has an intention to deceive by a fraudulent activity; is falsified for profit motives,

disregarding public health and safety; and that disputes concerning patents or trademarks must not be confused with falsification of medical products.

D

Delivery terms

are provisions determining the transport conditions until the moment of delivery of the goods.

E

Entrance quality control of medicines

is a quality control of medicines, active substances and excipients (that are received by business entity) that is carried out by visual inspection or analysis. Entrance control has provided by authorized person appointed by the manager of the business subject and responsible for the quality of the medicines entering to the pharmacy.

Essential Medicines List

The List of World Health Organization Essential Medicines is a model list of essential medicines created by the World Health Organization. This list is based on the 17th edition from March 2011.Essential medicines, as defined by the World Health Organization are "those drugs that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in appropriate dosage forms, at a price the community can afford." The WHO has published a model list of essential medicines. Each country is encouraged to prepare their own lists taking into consideration local priorities. At present over 150 countries have published an official essential medicines list.The core list presents a list of minimum medicine needs for a basic health care system, listing the most efficacious, safe and cost-effective medicines for priority conditions. Priority conditions are selected on the basis of current and estimated future public health relevance, and potential for safe and cost-effective treatment.

European Pharmacopoeia

is a legal act that is legislative in nature and contains general requirements for drugs, pharmacopoeial articles (monographs), and methods of quality control of drugs; an important mechanism of integration of national systems of different countries.

Extemporeus medicines

are the medicines that are made in the conditions of pharmacies according to the prescription.

F

FIP

FIP is the global federation representing three million pharmacists and pharmaceutical scientists worldwide. Founded in 1912, the International Pharmaceutical Federation is the global federation of national associations of pharmacists and pharmaceutical scientists and is in official relations with the World Health Organization.Through its 127 Member Organisations FIP represents and serves more than three million practitioners and scientists around the world. See more http://www.fip.org

Force-majeure

determines the independent of parties' circumstances, entailing breaking of contracts: military operations, revolutions, natural calamities and etc.

G

GCP

Good Clinical Practice is an international quality standard that as provided by International Conference on Harmonisation (ICH), an international body that defines standards, which governments can transpose into regulations for clinical trials involving human subjects. Good Clinical Practice guidelines includeprotection of human rights as a subject in clinical trial. It also provides assurance of the safety and efficacy of the newly developed compounds.

GDP

Good Distribution Practice or GDP deals with the guidelines for the proper distribution of medicinal products for human use. GDP is a quality warranty system, which includes requirements for purchase, receiving, storage and export of drugs, intended for human consumption. GDP regulates the division and movement of pharmaceutical products from the premises of the manufacturer of medicinal products, or another central point, to the end user thereof, or to an intermediate point by means of various transport methods, via various storage and/or health establishments.

General Sales List (GSL) medicines

are available to the public through many outlets, from supermarkets to the local garage. These are medicines which have a history of being safe and effective, meaning they can be sold by a person with no medical or pharmacy training.

GLP

Good Laboratory Practice generally refers to a system of management controls for laboratories and research organizations to ensure the consistency and reliability of results as outlined in the OECD Principles of GLP and national regulations. Good Laboratory Practice embodies a set of principles that provides a framework within which laboratory studies are planned, performed, monitored, recorded, reported and archived.

GMP

Good Manufacturing Practice or GMP (also referred to as 'GMP' or 'current Good Manufacturing Practice') is a term that is recognized worldwide for the control and management of manufacturing and quality control testing of foods and pharmaceutical products. GMP is designed to help assure the quality of drug products by ensuring several key attributes, including correctness and legibility of recorded manufacturing and control documentation.

GMP certification

is a system of rules, regulations and guidelines regarding the drugs, medical devices, diagnostic products and others; reflects a holistic approach and evaluates and adjusts the parameters of the actual production and laboratory testing.

GPP

The GPP Guidelines are based on the pharmaceutical care given by pharmacists. The International Pharmaceutical Federation first adopted the guidelines for Good Pharmaceutical Practice in 1993. The guidelines recommend for national standards to be set: the promotion of health; the supply of medicines, medical devices, patient self-care; improving prescribing and medicine use by pharmacists' activities. *Good pharmacy practice requires* that a pharmacist's first concern in all settings is the welfare of patients; the core of the pharmacy activity is the supply of medications and other health care products of assured quality, appropriate information and advice for the patient, and monitoring of the effects of use; an integral part of the pharmacist's contribution is the promotion of rational and economic prescribing and of appropriate use of medicines; the objective of each element of pharmacy service is relevant to the patient, is clearly defined and is effectively communicated to all those involved.

The International Pharmaceutical Federation first adopted the guidelines for Good Pharmaceutical Practice in 1993. The revised version of this document was endorsed by WHO in 1997 and subsequently approved by the FIP Council in 1997. The GPP Guidelines are based on the pharmaceutical care given by pharmacists. See more http://www.pharmainfo.net/reviews/good-pharmacy-practice-review

H

Health insurance

Health insurance is insurance against the risk of incurring medical expenses among individuals. Health insurance covers the cost of medical treatments.

I

Incoterms

are the official International Chamber of Commerce (ICC) rules for the interpretation of international trade terms that defines the respective roles of the buyer and seller in the arrangement of transportation and other responsibilities and clarify when the ownership of the goods takes place.

Insurance

Insurance is the equitable transfer of the risk of a loss, from one entity to another in exchange for payment. It is a form of risk management primarily used to hedge against the risk of a contingent, uncertain loss.

Insurance payments

Insurance payments are the insurance payments by insurance Company upon occurrence of insured event.

Insured person

Is the person, group, or property for which an insurance policy is issued.

Insurer

An insurer, or insurance carrier, is a company selling the insurance; the insured, or policyholder, is the person or entity buying the insurance policy. The amount of money to be charged for a certain amount of insurance coverage is called the premium. Risk management, the practice of appraising and controlling risk, has evolved as a discrete field of study and practice.

International Organization for Standardization (ISO)

is the world’s largest developer of voluntary International Standards. International Standards give state of the art specifications for products, services and good practice, helping to make industry more efficient and effective. Developed through global consensus, they help to break down barriers to international trade.

Intrachemists' quality control

is a set of preventive measures and control types that are made directly to the pharmacy and cover all stages of manufacturing drugs; provided by pharmacist-analyst.

L

License

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 the implementation of the licensed terms. License is a permission produced by the government (state organs) to the phisical and legal persons on realisation of definite activity including foreign trade on the export and import of medicines.**Licensee**

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

Licensing

Licensing is a procedure of delivery and cancellation of licenses, delivery of doublets oflicenses, conduct of the licensed businesses and licensed registers, controlafter implementation by the licensees of the licensed terms, delivery of ordersabout the removal of violations of the licensed terms, and also orders aboutthe removal of violations of legislation in the field of licensing.

M

Medicine pricing

is a process of determination of retail price of extemporal medicines (all the ingredients is taken into account, packing and tariff).

Ministry of healthcare

Ministry of healthcare is an executive body responsible for drafting and implementing government policy and legal regulation in the area of healthcare, mandatory health insurance, the production and distribution of pharmaceuticals for medical use, including disease prevention measures (such as AIDS and other infections), medical treatment, rehabilitation and appraisals (excluding medical-social and military medical appraisals), pharmaceuticals activities such as ensuring the quality, efficacy and safety of pharmaceuticals for medical use, the production and distribution of medical products, sanitary and epidemiologic welfare of the

population, medical and sanitary support for people employed in industries with dangerous working conditions, the medical-biological assessment of the health hazards associated with hazardous physical or chemical factors, the resort and recreation industry, as well as the management of state property and provision of state services related to healthcare, such as medical services, the introduction of modern medical technology, new disease prevention methods, diagnostics, treatment and rehabilitation methods, forensic tests and psychiatric appraisals, organisation of associate, university level, postgraduate and additional medical and pharmaceutical education, and resort and rehabilitation services.

N

National Pharmaceuticals Policy

A National Pharmaceuticals Policy is one that aims at ensuring that people get good quality drugs at the lowest possible price, and that doctors prescribe the minimum of required drugs in order to treat the patient's illness.

Narcotic drugs

are substances of natural or synthetic origin, preparations, plants that are dangerous to human health in the event of abuse included in the list of narcotic drugs, psychotropic substances and precursors (approved by the order of Cabinet of Ministers № 770).

O

Object-quantitative account (OQA)

is documented accounting operational traffic of drugs that are subject to special control, which is to prevent their uncontrolled use.

Obligatory medical insurance (OMI)

Obligatory Medical Insurance (OMI) is supported by a state program and serves as a prerequisite to obtaining government medical care free of charge. OMI covers only the most basic of treatments at government hospitals, in more complex cases one would have to pay for the treatment directly.

P

Prescription

is a medical document written out by specialist which has this right according to the legislation, on the basis of which making is carried out and/or sale medicines from pharmacies and pharmacy points by the set rules.

Prescription department

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

Prescription Medicine

means a medicinal product which may only be sold or supplied by retail in accordance with a prescription given by an appropriate practitioner. They are only available on a prescription from an authorized prescriber.

Prescription Only Medicine (POM)

means a medicinal product which may only be sold or supplied by retail in accordance with a prescription given by an appropriate practitioner. They are only available on a prescription from an authorized prescriber. The prescription may be either subsidized by the government, or a private prescription, the full cost of which is to be paid for by the patient.

Pharmacy

Pharmacy is an establishment of healthcare and it is a place, where the medicines and medicine products are delivered, checked and – to the small part – are produced.

Pharmacy 'P' medicines

are the medicines available only from pharmacies and can only be sold under the supervision of a pharmacist. Some 'P' medicines are products that have been deregulated from POM status, whereas others may have potential for misuse or require the supervision of a pharmacist during the sale. Other 'P' medicines need a

pharmacist’s expert knowledge of drug actions and possible interactions in order to be supplied to patients in certain situations.

Pharmaceutical care

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

Pharmaceutical care is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life. The philosophy of Pharmaceutical care was first described by Hepler and Strand in 1990. 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. More detail http://www.pharmacist.com/principles-practice-pharmaceutical-care.

Pharmaceutical industry

The pharmaceutical industry develops, produces, and markets drugs or pharmaceuticals licensed for use as medications.

Pharmacists' activity

Pharmacists' activity is an activity in providing population with medicines in order to improve the patients' quality of life using drug therapy.

Preamble of the contract

is a part of the contract where salesman and buyer and their legal status are determined.

Psychotropic drugs

are medicibes that included in the list of substances of natural or synthetic origin, drugs, natural materials that are able to induce a state of dependence and produce depressive or stimulating effect on the central nervous system, or impair the perception, emotion, thought or behavior and pose a risk to health.

Q

Quality control

is a set of preventive measures and control types that are made directly to the pharmacy and cover all stages of manufacturing drugs; provided by pharmacist-analyst.

R

Reimbursement

Reimbursement is an act of compensating someone for an expense. Health reimbursement means compensating someone medical expenses.

Responsible self-medication

This is the practice whereby individuals treat their ailments and conditions with medicines which are approved and available without prescription, and which are safe and effective when used as directed.

Responsible self-medication requires that:

Medicines used are of proven safety, quality and efficacy.

Medicines used are those indicated for conditions that are self-recognisable and for some chronic or recurrent conditions (following initial medical diagnosis). In all cases, these medicines should be specifically designed for the purpose, and will require appropriate dose and dosage forms.

The increasing importance of self-care and self-medication. The role of the pharmacist has been changing over the past two decades. The pharmacist is no longer just a supplier of medicines and a concocter of medicinal products, but also a team member involved in the provision of health care whether in the hospital, the community pharmacy, the laboratory, the industry or in academic institutions. Pharmaceutical care is growing in importance with the challenges of self-care. For pharmacists, their greater involvement in self-care means greater responsibility towards their customers and an increased need for accountability. The increase in self-care is due to a number of factors. These factors include: socioeconomic factors;

lifestyle; ready access to drugs; the increased potential to manage certain illnesses through self-care; public health and environmental factors; greater availability of medicinal products; and demographic and epidemiological factors.

S

Self medication

Self-medication is the selection and use of medicines by individuals to treat self-recognised illnesses or symptoms. Self medication can be defined as the use of medicine without any professional supervision. It aims to find the reason of self medication and make public aware about its effects and side effects. People use it for the treatment of any disease symptoms or minor ailments by their self initiative.

Storage

is the period of keeping a pharmaceutical production till the moment of its use.

T

Taxa laborum

Tariff (taxa laborum) is a payment for making of medications, which allows to compensate the charges, related to making of medications and to collect the incomes from the production activity.

V

Voluntarily medical insurance (VMI)

Voluntary medical insurance or purchased medical insurance is separately acquired by the individual or his employer. Purchased medical insurance tends to offer coverage that is far more comprehensive compared to OMI.

W

WHO

The World Health Organization (WHO) is a specialized agency of the United Nations (UN) that is concerned with international public health. It was established on 7 April

1948, with headquarters in Geneva, Switzerland, and is a member of the United Nations Development Group.The WHO's constitution states that its objective "is the attainment by all people of the highest possible level of health".

WHO identifies its role as one of six main objectives: providing leadership on matters critical to health and engaging in partnerships where joint action is needed;

shaping the research agenda and stimulating the generation, translation and dissemination of valuable knowledge;

setting norms and standards and promoting and monitoring their implementation;

articulating ethical and evidence-based policy options;

providing technical support, catalyzing change, and building sustainable institutional capacity; and

monitoring the health situation and assessing health trends.

For notes

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