

Tehran University of Medical Sciences  
Medical Ethics and History of Medicine Research Center  
In collaboration with Pharmaceutical Sciences Research Center  
CODE OF ETHICS FOR THE NATIONAL PHARMACEUTICAL SYSTEM

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## INTRODUCTION

Pharmacists, as a group of health care providers, assist people for optimum use of drugs and are the trustee providers of pharmacy services. Pharmacists' Code of Ethics sets principles that pharmacists and pharmacy technicians must comply with. Pharmacists' Code of Ethics serves as guidance on the expected professional performance of the professionals in this field. In addition to supporting and guiding professionals in their work and decisions, it informs the public of the standard conducts they can expect from professionals. The principles of the Code of Ethics are mandatory, and every pharmacist, irrespective of being in practice or not, must comply with the code and apply them to their daily functions. In other words, the professional performance of pharmacists shall be evaluated based on this code hereinafter.

The recipients of pharmacy services are patients. In the present document, patient(s) refer to any individual or group of people who receive pharmacy services or become affected by them. When veterinary pharmacy services are provided, the term patient refers to the animals being cared for. The present code is founded on eight principles that state the principles of professional ethics in pharmacy. These eight principles and their explanations express the duties of a pharmacist and their definitions are as follows:

## GLOSSARY

### Autonomy

Patient: a person who receives professional pharmacy services or is affected by it.

## 1. PRINCIPLE OF RESPECT FOR PATIENT DIGNITY AND AUTONOMY

The main duty of a pharmacist is patient care. Pharmacists should encourage patients to take part in decision making, and respect their right to confidentiality, privacy, and receiving understandable information.

### OBLIGATIONS

1.1. Patients' physical state, social rank, socio-economic status, religion, culture, and race should not affect presenting information to them.

1.2. Patients' informed consent is necessary for providing professional services, treatment, and care for patients, as well as for using patient information. For this purpose, while respecting patient autonomy, pharmacists provide understandable information to patients with honesty and confidence so that they can participate in making decisions in matters related to their disease. Pharmacists explain terminology that patients find hard to understand. Providing drug information is not exclusive to prescription medication only; it includes over-the-counter drugs, herbal medicine, supplements, and other health products as well.

1.3. To ensure safe and efficacious drug consumption, pharmacists should inform patients of drug interactions, limitations of drug effect, side effects, directions for use, limitations of use, and proper actions in case of side effects, as well as optimum storing conditions and proper disposal method of expired drugs.

1.4. The provided information should not be influenced by financial or marketing interests of an individual or group. Pharmaceutical information should be based on scientific evidence, ethical principles, and legal standards, free of partiality in favor of the patient, physician, or community.

1.5. Pharmacists should respect the dignity of all patients regardless of their decision making capacity.

1.6. Respecting the principle of confidentiality, pharmacists should make every effort to keep patients' secrets.

1.7. When applicable, pharmacists should explain the reasons that withhold them from filling a prescription.

1.8. Conducting research at the pharmacy is allowed only after obtaining approval from the appropriate regulatory authorities, permission from the Committee of Ethics in Research, and informed consents from the patients.

1.9. While on duty, pharmacists should wear a white coat and a name tag, and sign prescriptions

with a pharmacy stamp that states the registration number with the National Medical Council.

1.10. Should a patient ask for a refill to continue their prescription medication for more than 72 hours, pharmacists should consult the prescribing physician after obtaining the patient's informed consent.

1.11. Should a patient's health call for a pharmacist to reveal his/her secrets to other members of the health care team, the pharmacist should obtain patient consent.

1.12. Delivering drugs to children younger than 12 years is prohibited and should be done in the presence of their parents.

1.13. Should pharmacists decide that revealing teenage patients' secret is necessary for their own or their families' safety, in cases such as drug addiction and attempted suicide or homicide, they may consult with their physicians, psychologists, parents, or legal guardians.

1.14. Cases in which pharmacists are permitted to violate the principle of confidentiality include: patient consent, legal obligation, protecting patients from secondary harm (danger should be serious and imminent, which can only be prevented by violating confidentiality; even then, disclosures should be limited to a minimum necessary).

1.15. Pharmacists are obligated to respect confidentiality in regards to their work place (pharmacy) as well.

1.16. Pharmacists should respect patients' rights to accept or refuse treatment, care, and other professional services.

1.17. Pharmacists are obligated to provide an itemized description of incurred charges upon patients' request.

#### 2. PRINCIPLE OF BENEFICENCE

The ultimate goal in providing pharmacy services is optimizing drug therapy according to patients' needs, interests, cultural values, and beliefs, and the needs of the community.

#### OBLIGATIONS

2.1. To provide patient-centered care, and to enhance patient health, pharmacists should strive to optimize drug consumption which is one of the basic principles of the pharmacy profession.

2.2. Constructive cooperation requires an effective rapport and the ability to recognize patients' needs. For patients without legal decision making capacity, pharmacists should consult their legal surrogates.

2.3. To present drugs to the consumer, pharmacists must first verify the prescription and assess its suitability for the diagnosis. They must keep a clear and readable log with all relevant information.

2.4. At the pharmacy or any site they are responsible for, pharmacists must be involved with the sale of any type of drug including supplements, herbal products, over-the-counter medication, and other items available at the pharmacy. For this purpose, they should obtain sufficient information from the patient to ensure the correct item is sold.

2.5. Should a pharmacist's religion or ethical beliefs prevent them from providing a particular service, he/she is obligated to inform another person or persons with special authority, and refer patients to them.

2.6. Pharmacists are obligated to provide patients with information for continued receipt of pharmacy services when services are interrupted due to situations such as natural disasters or situations in which it is difficult to contact the pharmacy.

2.7. The interior layout of the pharmacy must accommodate easy interaction between consumer and pharmacist as well as patient privacy.

2.8. Pharmacists must strive to enhance the health of the community.

#### 3. PRINCIPLE OF NON-MALEFICENCE

Pharmacists must refrain from maleficence to patients and the community.

#### OBLIGATIONS

3.1. Should a pharmacist not be able to provide services for any reason, he/she must inform responsible authorities.

3.2. The patient-pharmacist relationship should be in a way that does not hurt the patient or create any risk of harm, and at the same time, should not compromise pharmacists' professional independence or commitments.

3.3. Pharmacists' work conditions such as hardship, insufficient salary, employer's demands, etc. should not compromise the quality of pharmacy services.

3.4. Technicians can be assigned pharmacy duties that are appropriate for their knowledge, skills, and experience.

- Υ.ο. Pharmacists must only provide drugs whose qualities they are assured of. This applies to supplements and herbal products as well.
- Υ.ϒ. During working hours of a pharmacy, all affairs concerning the distribution of drugs must be supervised by the managing pharmacist.
- Υ.ϛ. Should there be sufficient evidence of error, deletion, or vagueness in a prescription, pharmacists should consult the prescribing physician and record details.
- Υ.Α. The managing pharmacist must participate in the Drug Consumption Monitoring Program.
- Υ.Ϡ. Should there be any serious problem such as serious drug reactions or interactions, pharmacists must consult the prescribing physician and contact the Center for Adverse Drug reactions (ADR) of the Ministry of Health and Medical Education in due time.
- Υ.ϑ. Should there be sufficient evidence of drug misuse, overuse, or incorrect use of prescribed medication, pharmacists must inform the prescribing physician.
- Υ.ϒϑ. Drugs and poisons that are dangerous for children must have child-proof packaging and be stored away from their reach unless the patient is not able to open it, there is a request not to have child-proof packaging, or there is some reason that the drug should not be placed in such packaging.
- Υ.ϒϒ. All pharmacy drugs must be placed in an area under full control and care of the pharmacist.
- Υ.ϒϛ. Pharmacists can perform only certain diagnostic tests and screening services for which they have received training and obtained the necessary license from responsible authorities.
- Υ.ϒϜ. Disposal of waste material must be under the supervision and care of pharmacists.
- Υ.ϒο. Upon identifying a pharmacy error, pharmacists must first inform the patient, and then make every effort to minimize harm to the patient based on protocols of the workplace or related regulations.

#### Ξ. PRINCIPE OF JUSTICE

Pharmacists must help enhance the health of the community through fair and just functioning.

#### OBLIGATIONS

- Ξ.ϑ. Pharmacists must provide highest standard of pharmacy services in presenting patient-centered pharmacy services.
- Ξ.ϒ. In distributing resources, pharmacists must be fair and just and maintain a balance between the needs of the community and the patient, understand limitations of available resources, and be aware of circumstances that violate their ethical responsibilities.
- Ξ.ϛ. In the absence of a specific drug or special services needed by the patient, pharmacists must guide the patient as much as possible.
- Ξ.Α. Financial interests must not affect pharmacists' impartiality in their professional judgment or pharmacy care standards, and must not impair their collaboration with the other members of the health care team.
- Ξ.ο. The ethical responsibilities of pharmacists must not be sacrificed for financial interests of the pharmacy owner.

#### ο. PRINCIPLE OF EMPATHY

Pharmacists must care with respect and empathy.

#### OBLIGATIONS

- ο.ϑ. Pharmacists must empathize with patients and ask them to express their concerns and worries.
- ο.ϒ. Pharmacists must act in order to resolve problems related to the use of drugs and remove obstacles related to patient activities (caused by the use of drugs) accounting for their special circumstances (physical or mental disability).
- ο.ϛ. Pharmacists must empathize with colleagues and establish mutual understanding with them.
- ο.Α. Empathy with patients must be with respect, honesty, and explicitness.

#### ϒ. PRINCIPLE OF PROFESSIONAL EXCELLENCE

Pharmacists must actively engage in updating and practicing up-to-date knowledge to maintain their professional qualifications.

#### OBLIGATIONS

- ϒ.ϑ. Pharmacists must be aware of professional and ethical codes, regulations, guidelines, and announcements related to the area of their activities.
- ϒ.ϒ. Pharmacists must have a socially acceptable conduct in their professional activities and beyond professional boundaries, and must refrain from actions that can cause professional notoriety or public mistrust.
- ϒ.ϛ. Pharmacists must provide professional services and information appropriate for their professional rank without making any unfounded claims.

٦.٤. Pharmacists must provide appropriate feedback to manufacturers, importers, and distributors of drug products about the quality, packaging, and shape of the drug in order to achieve qualitative and quantitative improvement.

#### V. PRINCIPLE OF HONESTY

Pharmacists must maintain professional independence, rectitude, and honesty.

#### OBLIGATIONS

V.١. Exchanging gifts among pharmacists, pharmaceutical companies, and other members of the health care team must not affect their independence, professional judgment, their ability to function professionally, or performing their legal responsibilities.

V.٢. Pharmacists must have appropriate supervision over pharmacy personnel and accept responsibility of all activities performed under their supervision.

V.٣. Pharmacists must be present at the pharmacy during all working hours.

V.٤. Pharmacists may receive money only for the provided services according to pre-defined regulations and guidelines.

V.٥. Pharmacists must not be engaged in the trade of any drug or product that can risk their professional position; these include cigarettes, non-pharmaceutical narcotics, food products, illegal supplements, and illegal cosmetics and beauty products.

V.٦. Pharmacists are forbidden to perform piercing of body parts or any service that lacks a therapeutic purpose.

V.٧. The presentation and contents of posters and other advertisement tools used in pharmacies should not violate professionalism.

V.٨. For advertisement, pharmacists must only use methods that are appropriate for professional commitments that necessitate facilitated services. Advertisement should not make the public think that drugs are similar to other food or health products. In advertising for drugs, pharmacists' professional commitments and responsibilities must be observed, and emphasis must be placed on the benefits of drugs, not their price.

V.٩. The contents of advertisements must be true, factual, and accurate; they should not contain any claim that cannot be proved, may take advantage of public trust, or might deceive them.

V.١٠. Pharmacists must provide patients with drugs, herbal products, and supplements in necessary amounts.

V.١١. Advertisements should not lead to misuse, unsafe use, unnecessary use, or overuse of drugs, herbal products or supplements.

V.١٢. Pharmacists must provide thorough explanation regarding the existence of sufficient scientific evidence about the risks and benefits of supplements and herbal drugs for the patient's condition.

V.١٣. Pharmacists should respond to complaints and criticisms with honesty and in a well-mannered, polite way.

V.١٤. Pharmacists must have a logical relationship with patients within the limits of their profession. This means that pharmacists are ethically responsible before their community and must strive to deliver the most appropriate drug therapy to people, improve patient health, and maintain public trust towards their profession.

V.١٥. In selling drugs, pharmacists must observe the codes and regulations set by the Food and Drug Organization of the Ministry of Health and Medical Education.

V.١٦. Pharmacists must not change the type or amount of prescribed drugs without informing the physician.

V.١٧. Offering any money or gift as incentive for referring patients to the pharmacy is unethical.

#### ٨. PRINCIPLE OF COOPERATION

Pharmacists must respect the skills and qualities of other health care providers, and cooperate with them towards enhancing health service provision.

#### OBLIGATIONS

٨.١. Pharmacists must develop, maintain, and expand professional relationships with peers and colleagues and other health service providers for the purpose of promoting community health.

٨.٢. Pharmacists should aim to perform optimally as a member of the health care team.

٨.٣. Pharmacists must respect the qualities and capabilities of other related organizations and professions.

٨.٤. When special knowledge and skills are required, while maintaining confidentiality, pharmacists must refer patients accordingly after obtaining informed consent.

٨.٥. Despite the close professional relationship between pharmacists and other members of the

health care team, pharmacists must restrict their participations to activities that do not impact their professional independence or judgment provided that no special financial relationship is created. These relationships should not create any limitation for patients' choice of pharmacists or other team members.

A.Ⅶ. Choosing manufacturers, importers, and distributors of drugs must be based on the quality of services and products rather than their prices, incentives, or special privileges.

A.V. Pharmacists must not belittle the professional functions of other pharmacists, pharmacies, or members of the health care team.

#### ETHICS GUIDELINE FOR PHARMACEUTICAL MANUFACTURERS

##### Ⅰ. ETHICAL OBLIGATIONS TOWARDS CONSUMERS (DISTRIBUTORS)

Ⅰ.Ⅰ Providing high quality services including the quality of drugs, proper pricing, and timely delivery.

Ⅰ.Ⅱ Easy access to the sales unit of the company.

Ⅰ.Ⅲ Providing a summary of information about drugs and products such as indications, side effects, contraindications, and warnings.

Ⅰ.Ⅳ Prohibition of granting cash and non-cash prizes unless in exceptional cases and with permission of relevant managers and in accordance with the principles of the ethics of competition

Ⅰ.Ⅴ Applying the ethics of hospitality in given situations such as business meetings or when accompanying other pharmaceutical companies in conventions is permissible provided that it does not seem inappropriate and business decisions are not affected.

Ⅰ.Ⅵ Commitment to the ethics of competition:

Ⅰ.Ⅵ.Ⅰ Disclosing all aspects of competition including sources of raw material, method of disposing waste material, methods of production, packaging, and the amount of gifts and incentives.

(Disclosures should state the nature of gifts such as present, compensation for loss, labor fee, commission, and should specify the items or amounts given.)

Ⅰ.Ⅵ.Ⅱ Refrainment from the share or exchange of information regarding policies for pricing, discounting, advertisement, exclusive rights, warranties, and sales conditions with competitors, whether at business meetings or at private or friendly social gatherings.

Ⅰ.Ⅵ.Ⅲ Refrainment from falsifying the services or products of competitors.

Ⅰ.Ⅵ.Ⅳ Fair competition within the laws of competition, and announcing it to company employees, especially marketing, sales, and purchasing units.

Ⅰ.Ⅵ.Ⅴ Refrainment from obtaining information through providing false information, theft, violating privacy, or force.

##### Ⅱ. ETHICAL OBLIGATIONS TOWARDS PATIENTS

Ⅱ.Ⅰ Enhancing the quality of drugs and products by obtaining the appropriate and high quality raw material from qualified and trusted resources.

Ⅱ.Ⅱ Fair and suitable pricing.

Ⅱ.Ⅲ Providing a brochure stating a summary of side effects, precautions, warnings, contraindications, as well as effectiveness for the stated indication.

Ⅱ.Ⅳ Conducting clinical experiments in accordance with standards and clear guidelines to determine the safety and efficacy of drugs in order to advance knowledge and serve the community rather than verifying the drug for financial gain, etc.

Ⅱ.Ⅴ Conducting clinical studies on the safety and effectiveness of drugs in the science department of the factory before marketing, rather than after its introduction to the market or through prescribing physicians.

Ⅱ.Ⅵ The purpose of holding and participating in meetings and conventions should be improving patient care and enhancing the quality of services and products of the company, not just presenting and advertising them.

Ⅱ.Ⅶ Giving priority to patient benefits in case there is conflict of interest between different aspects of the charter (such as conflict between the interests of shareholders and patients)

##### Ⅲ. ETHICAL OBLIGATIONS TOWARDS PHYSICIANS AND HEALTH CARE PROVIDERS

Ⅲ.Ⅰ Having an honest and clear relationship with the medical society based on scientific evidence and providing accurate information without exaggeration.

Ⅲ.Ⅱ Publishing honest and unbiased results of clinical studies regarding the safety and efficacy of drugs.

Ⅲ.Ⅲ Prohibition of granting cash and non-cash gifts to physicians unless in exceptional cases and with

permission of relevant managers and in accordance with the principles of the ethics in order to gain the trust of physicians for making decisions based on patients' best interest and the quality and efficacy of drugs.

Կ.Ճ Offering low-cost promotional gifts such as pens, calendars, notebooks, brochures, or guideline pamphlets which are tools for physicians is permissible. It is also permissible to offer promotional keepsakes with inscriptions of the name of the drug or company which have little monetary value.

Կ.Ծ Applying the ethics of providing financial support in given situations such as scientific meetings or events is permissible provided that it does not seem inappropriate and physicians' decisions are not affected.

Կ.Դ Invitation to conventions and meetings:

Կ.Դ.1 The sole purpose should be improving patient care and enhancing the quality of products and services.

Կ.Դ.2 The material presented at conventions should concern appropriate issues, and expressed in a professional and scientific manner.

Կ.Դ.3 The venue should be chosen to satisfy the comfort of the participants in terms of proximity, expenses, accommodation, and must be appropriate for the type of convention and its audience.

Կ.Դ.Է Decisions for support and sponsorship must be in accordance with the law and not to entice physicians.

Կ.Դ.Ծ Should the invited physicians also be government employees or authorities, conflict of interest and role in decision making must be considered.

Կ.Դ.Դ. Inviting physicians' family members is not in line with scientific or professional ethics.

#### Է. ETHICAL OBLIGATIONS TOWARDS THE COMMUNITY AND ENVIRONMENT

Է.1 All pharmaceutical companies are mandated to develop an ethics charter of their own in accordance with ethical principles and the comprehensive Code of Ethics of the National Pharmaceutical System.

Է.2 Preparation and manufacture of biocompatible products in accordance with bioenvironmental laws and codes.

Է.3 Disposal of waste material in accordance with bioenvironmental standards.

Է.Զ Refrainment from bribery in any form to governmental entities in order to facilitate customs processes, drug registration, permit obtainment, etc.

Է.Ծ Adherence to the current codes and regulations of the pharmaceutical industry including research, development, manufacture, marketing, sales, and distribution of drugs.

Է.Դ Supporting charitable institutions, non-profit organizations, and humanitarian programs.

#### Ծ. ADVERTISEMENT

Ծ.1 In advertisement and provision of drug information for health care providers, especially physicians, accuracy, honesty, impartiality, and realism must be observed, while falsified and exaggerated advertisement about drugs and supplements must be avoided.

Ծ.2 Advertising for new drugs or new indications for use of drugs is permissible only by a permit from the Ministry of Health and Medical Education.

Ծ.3 In advertising for new drugs, any financial relationship between researchers of published manuscripts and the pharmaceutical company, or any other form of conflict must be disclosed and stated.

Ծ.Է In addition to drug information, advertisements must contain the brand name of the drug, name of the active ingredient(s), class of drug, name and address of the manufacturer/importer.

Ծ.Ծ In providing drug information and referring to clinical trials, only registered trials which have obtained relevant approvals may be cited. In terms of supplements, advertisements must be based on realism and clinical and scientific evidence.

Ծ.Դ When referring to clinical trials or other studies such as meta-analyses, the complete description of the published article must be stated.

Ծ.Վ To introduce drugs to physicians and other health care providers, they must be provided with a limited number of drug samples which may not be sold or prescribed to patients.

Ծ.Ա Should there be urgent need for drug safety information dissemination, drug recall, restricted distribution or use, or other restrictions, required information must promptly be made available to patients and doctors, pharmacies, distributing companies, and other relevant entities.

Ծ.Գ Drug information on websites should be provided for professionals and patients separately.

Ծ.1Ը Pharmaceutical companies must by no means pay physicians for participating in seminars and meetings.

o.11 The relationship between physicians and companies should be via scientific and specialty societies. To avoid any discrimination or injustice, attendees should disclose their interests as they convey scientific achievements of the convention to the members of the society, specialists, and researchers of the field during a half-day conference upon their return.

o.12 All financial sponsorships provided by drug manufacturers and importers for national and international conventions must be stated in the abstract book and the website of the convention.

o.13 The nature of all financial support provided by drug manufacturers and importers for health research projects must be described.

#### ETHICS GUIDELINE FOR PHARMACEUTICAL IMPORTERS

##### 1. ETHICAL OBLIGATIONS TOWARDS CONSUMERS (DISTRIBUTORS)

1.1 Choosing the source company based on the good reputation of the company, the quality and variety of products and services, and proper pricing and delivery of goods.

1.2 Providing high quality services in terms of the quality of drugs, proper pricing, and timely delivery.

1.3 Easy access to the sales unit of the company.

1.4 Employee functioning based on respect and solemnity in work within their qualifications and powers.

1.5 Providing a summary of information about drugs and products such as indications for use, side effects, contraindications, and precautions.

1.6 Prohibition of granting cash and non-cash prizes unless in exceptional cases after proper arrangements with authorities and in accordance with the principles of the ethics of competition.

1.7 Applying the ethics of hospitality in given situations such as business meetings or when accompanying other pharmaceutical companies in conventions is permissible provided that it does not seem inappropriate and business decisions are not affected.

1.A Commitment to the ethics of competition:

1.A.1 Disclosing all aspects of competition including sources of raw material, method of disposing waste material, methods of production and packaging, and the amount of gifts and incentives. (Disclosures should state the nature of gifts such as it being a present, compensation for loss, labor fee, or commission, and should specify the items or amounts given.)

1.A.2 Refrainment from the share or exchange of information regarding policies for pricing, discounting, advertisement, exclusive rights, warranties, and sales conditions with competitors, neither at business meetings nor at private or friendly social gatherings.

1.A.3 Refrainment from falsifying the products or services of competitors.

1.A.4 Fair competition within the laws of competition, and announcing it to company employees, especially marketing, sales, and purchasing units.

1.A.5 Refrainment from obtaining information through provision of false information, theft, violating privacy, or force.

##### 2. ETHICAL OBLIGATIONS TOWARDS PATIENTS

2.1 Choosing the source company based on the good reputation of the company, the quality and variety of products and services, and proper pricing and delivery of goods.

2.2 Fair and proper pricing.

2.3 Providing a brochure stating a summary of side effects, precautions, warnings, contraindications, as well as effectiveness for the stated indication.

2.4 The purpose of holding and participating in meetings and conventions should be improving patient care and enhancing the quality of services and products of the company, not just presenting and advertising them.

2.5 Refrainment from deceiving patients by providing drugs other than that stated in the labeling.

##### 3. ETHICAL OBLIGATIONS TOWARDS PHYSICIANS AND HEALTH CARE PROVIDERS

3.1 Having an honest and clear relationship with the medical society which is based on scientific evidence, and providing accurate information free of exaggeration.

3.2 Publishing honest and unbiased results of clinical studies regarding the safety and efficacy of drugs.

3.3 Prohibition of granting cash and non-cash gifts to physicians unless in exceptional cases and only after informing responsible authorities and in accordance with the codes of ethics in order to gain the trust of physicians for making decisions based on patients' best interest and the quality and efficacy of drugs.

۳.۵ Offering low-value promotional gifts such as pens, calendars, notebooks, brochures, or guideline pamphlets which are tools for physicians is permissible. It is also permissible to offer promotional keepsakes with inscriptions of the name of the drug or company which have little monetary value.

۳.۵ Hospitality or providing meals in given situations such as scientific meetings or events is permissible provided that it does not seem inappropriate and physicians' decisions are not affected.

۳.۶ In terms of invitation to conventions and meetings:

۳.۶.۱ The sole purpose should be improving patient care and enhancing the quality of products and services.

۳.۶.۲ The material presented at conventions should concern appropriate issues, and expressed in a professional and scientific manner.

۳.۶.۳ The venue should be chosen to satisfy the comfort of the participants in terms of proximity, expenses, accommodation, and must be appropriate for the type of convention and its audience.

۳.۶.۴ Decisions for support and sponsorship must be in accordance with the law and not to entice physicians.

۳.۶.۵ Should the invited physicians also be government employees or authorities, their conflict of interest and decision making power must be considered.

۳.۶.۶. Inviting physicians' family members is not in line with scientific or professional ethics.

#### ۴. ETHICAL OBLIGATIONS TOWARDS THE COMMUNITY AND ENVIRONMENT

۴.۱ All pharmaceutical companies are mandated to develop an ethics charter of their own in accordance with ethical principles and the comprehensive Code of Ethics of the National Pharmaceutical System.

۴.۲ Adherence to standards of bioenvironmental, energy saving, recycling, reduction of pollutants, and sanitary disposal of potential waste material.

۴.۳ Refrainment from bribery in any form to governmental entities in order to facilitate customs processes, drug registration, permit obtainment, etc.

۴.۴ Adherence to the current regulations of the pharmaceutical industry including research, development, marketing, sales, and distribution of drugs.

۴.۵ Supporting charitable institutions, non-profit organizations, and humanitarian programs.

#### ۵. ETHICAL OBLIGATIONS TOWARDS NATIONAL INTEREST

۵.۱ The ultimate goal of importing companies should be improving the science and technology of the pharmaceutical industry of the country. For this purpose, importing companies must strive in line with the policies of the Food and Drug Organization of the Ministry of Health and Medical Education to transfer the technology and knowledge related to their registered drug to the country.

۵.۲ Should the domestic production of a given drug be of sufficient quantity and quality, importing the same drug is not fair.

۵.۳ Choosing a drug for import must be based on the principle of being fair in allocating resources and the true needs in the field of health.

#### ۶. ADVERTISEMENT

۶.۱ In advertisement and provision of drug information for health care providers, especially physicians, accuracy, honesty, impartiality, and realism must be observed, while falsified and exaggerated advertisement about drugs and supplements must be avoided.

۶.۲ Advertising for new drugs or new indications for use of drugs is permissible only by a permit from the Ministry of Health and Medical Education. In advertising for new drugs, any financial relationship between researchers of published manuscripts and the importing company, or any other form of conflict must be disclosed and stated.

۶.۳ In addition to drug information, advertisements must contain the brand name of the drug, name of the active ingredient(s), class of drug, name and address of the manufacturer/importer.

۶.۴ In providing drug information and referring to clinical trials, only registered trials which have obtained relevant approvals may be cited. In terms of supplements, advertisements must be based on realism and clinical and scientific evidence.

۶.۵ When referring to clinical trials or other studies such as meta-analyses, etc., the complete description of the published article must be stated.

۶.۶ To introduce drugs to physicians and other health care providers, they must be provided with a limited number of samples which may not be sold or prescribed to patients.

۶.۷ Should there be urgent need for information dissemination regarding the safety of a given product, and a need for drug recall, restricted distribution or use, or other restrictions, required information must promptly be made available to patients and doctors, pharmacies, distributing

companies, and other relevant organizations.

7.8 Drug information on websites should be provided for professionals and patients separately.

7.9 Pharmaceutical companies must by no means pay physicians for participating in seminars and meetings.

7.10 The relationship between physicians and companies should be via scientific and specialty societies. To avoid any discrimination or injustice, attendees should disclose their interests as they convey scientific achievements of the convention to the members of the society, specialists, and researchers of the field during a half-day conference upon their return.

7.11 All financial sponsorships provided by drug manufacturers or importers for national and international conventions must be stated in the abstract book and the website of the convention.

7.12 The nature of all financial support provided by drug manufacturers and importers for health research projects must be described.

## ETHICS GUIDELINE FOR PHARMACEUTICAL DISTRIBUTORS

### 1. ETHICAL OBLIGATIONS TOWARDS CONSUMERS (PHARMACIES)

1.1 Providing high quality services in terms of the quality of drugs, proper pricing, and timely delivery.

1.2 Easy access to the sales unit of the company.

1.3 Treating consumers with respect and honesty, and respecting the confidentiality of their information.

1.4 Providing a summary of information about drugs and products such as indications for use, side effects, contraindications, and precautions.

1.5 Prohibition of granting cash and non-cash prizes and gifts.

1.6 Refrainment from biased or exaggerated advertisement of their products and refrainment from falsifying the products or services of competing companies.

1.7 Refrainment from obtaining information through provision of false information, theft, violating privacy, or force.

1.8 Fair competition within the codes of competition, and announcing it to company employees, especially sales and purchasing units.

1.9 Refrainment from the share or exchange of information regarding policies for pricing, discounting, advertisement, exclusive rights, warranties, and sales conditions with competitors, neither at business meetings nor at private or friendly social gatherings.

1.10 Refrainment from creating false competition among manufacturers or importers which can lead to a decline in the quality of the drug.

1.11 Absolute refrainment from unethical financial actions such as laundering.

1.12 Disclosure of all aspects of competition including the source of drug, and the amount of prizes and gifts. (Disclosures should state the nature of gifts such as present, compensation for loss, labor fee, commission, and should specify the items or amounts given.)

### 2. ETHICAL OBLIGATIONS TOWARDS PATIENTS

2.1 Prioritizing enhancement of the quality of services and community health.

2.2 Fair and proper pricing.

2.3 Choosing the manufacturing or importing company based on the quality of products and services, and not just proper pricing or special privileges.

2.4 Avoiding circumstances of conflict of interest; should such circumstances arise, priority should be given to the interest of the patients (such as conflict of interest between shareholders and patients).

2.5 Preserving drugs in accordance with the storing and distribution instructions.

### 3. ETHICAL OBLIGATIONS TOWARDS PHYSICIANS AND HEALTH CARE PROVIDERS

3.1 Having an honest and clear relationship with the medical society which is based on scientific evidence, and providing accurate information free of exaggeration.

3.2 Prohibition of granting cash and non-cash gifts to physicians unless in exceptional cases and only after informing responsible authorities and in accordance with the codes of ethics in order to gain the trust of physicians for making decisions based on patients' best interest and the quality and efficacy of drugs.

3.3 Offering low-value promotional gifts such as pens, calendars, notebooks, brochures, or guideline pamphlets which are tools for physicians is permissible. It is also permissible to offer promotional keepsakes with inscriptions of the name of the drug or company which have little monetary value.

## Σ. ETHICAL OBLIGATIONS TOWARDS THE COMMUNITY AND ENVIRONMENT

Σ.1 All pharmaceutical companies are mandated to develop an ethics charter of their own in accordance with ethical principles and the comprehensive Code of Ethics of the National Pharmaceutical System.

Σ.2 Refrainment from bribery in any form to governmental entities in order to facilitate administrative processes of the company.

Σ.3 Adherence to the current regulations and codes of purchasing, sales, and distribution of drugs.

Σ.4 Supporting charitable institutions, non-profit organizations, and humanitarian programs.

### ο. ADVERTISEMENT

ο.1 In advertisement and provision of drug information for health care providers, especially physicians, accuracy, honesty, impartiality, and realism must be observed, while falsified and exaggerated advertisement about drugs and supplements must be avoided.

ο.2 Advertising for new drugs or new indications for use of drugs is permissible only by a permit from the Ministry of Health and Medical Education.

ο.3 In addition to drug information, advertisements must contain the brand name of the drug, name(s) of the active ingredient(s), class of drug, name and address of the manufacturer/importer.

ο.4 In providing drug information and referring to clinical trials, only registered trials which have obtained relevant approvals may be cited. In terms of supplements, advertisements must be based on realism and clinical and scientific evidence.

ο.5 When referring to clinical trials or other studies such as meta-analyses, the complete description of the published article must be stated.

ο.6 To introduce drugs to physicians and other health care providers, they must be provided with a limited number of samples which may not be sold or prescribed to patients.

ο.7 Should there be urgent need for information dissemination regarding the safety of a given product, and a need for drug recall, restricted distribution or use, or other restrictions, required information must promptly be made available to patients and doctors, pharmacies, distributing companies, and other relevant organizations.

ο.8 Drug information on websites should be provided for professionals and patients separately.

ο.9 Pharmaceutical companies must by no means pay physicians for participating in seminars and meetings.

ο.10 All financial sponsorships provided by drug manufacturers or importers for national and international conventions must be stated in the abstract book and the website of the convention.

1.12 The nature of all financial support provided by drug manufacturers and importers for health research projects must be described.

## ETHICS GUIDELINE FOR THE FOOD AND DRUG ORGANIZATION

### 1. ETHICAL OBLIGATIONS OF THE FOOD AND DRUG ORGANIZATION TOWARDS THE COMMUNITY AND TARGET POPULATIONS

1.1 The core responsibility of the Food and Drug Organization is individual and organizational accountability and transparency in pharmaceutical policymaking with the aim to provide safe and effective drugs in due time to improve the health of the community.

1.2 In light of sensitive positions, employment at the Food and Drug Organization requires maximum accountability and ethical considerations.

1.3 In light of the regulatory role of the Food and Drug Organization for consumers and pharmaceutical factories, the employees of this organization must be especially aware to avoid any type of conflict between personal interests and their official commitments; each member of the policymaking committee is mandated to inform the committee of any conflict of interest which may interfere with ethical actions; these include direct and indirect conflicts (any agreement which leads to continuing previous work (financial) relations or establishing new work (financial) relations) as well as conflicts that existed before being appointed.

1.4 These conflicts must be reported to every member of the committee in writing.

1.5 After disclosing conflicts of interest, the person involved must not participate in decision-making, unless the conflict has been completely disclosed and other members of the committee agree to his/her involvement in decision-making, and their agreement is approved by the head of the committee.

1.6 The highest authority of the committee should consider the status of the National Taxation System and develop the necessary legal tool for every fiscal year to protect the interests of patients and support the continuation of the pharmaceutical market.

1.V The staff of the Food and Drug Organization should strive to find more efficient and cost-effective methods for facilitating affairs.

1.A The staff of the Food and Drug Organization should act fairly and avoid any discrimination, partiality, and conflict of interest.

1.9 It is necessary to establish a group for the purpose of regulating conflict of interest in the organization, and presenting suggestions for new codes and policies when needed.

1.10 The employees of the Food and Drug Organization must obtain the approval of the organization for all extra-organizational activities; this excludes membership in charity, religious, social, entertainment, public service, and civil societies or other similar non-commercial organizations.

1.11 The staff of the Food and Drug Organization must not accept managerial roles in target companies, be in their employment simultaneously, or form any type of executive or financial collaboration with such companies whether full time, part time, or as part of a project.

1.12 Any of the members of the committee or employees who have access to individual or company information and documents is prohibited to disclose such information directly or indirectly to any real or legal person or the court, unless stated by law or approved by real and legal persons. Staff who have access to confidential information in light of their position must be responsible for saving such information, and strive to avoid their disclosure. In addition, they must refrain from using such information for their personal interest.

1.13 The employees of the Food and Drug Organization must not receive anything of monetary value as a gift, reward, loan, etc., from drug manufacturers, importers, or distributors, or other related real or legal persons, whether directly or indirectly.

## 2. ETHICAL OBLIGATIONS OF THE FOOD AND DRUG ORGANIZATION TOWARDS DRUG MANUFACTURERS, IMPORTERS, DISTRIBUTORS, AND PHARMACIES

2.1 Predictability of laws, codes, and commitments.

2.2 Accountability.

2.3 Liability.

2.4 Impartiality in providing services and transparent and fair notification of codes to all companies (public and private) and related entities.

2.5 Confidentiality and adherence to privacy of company information.

2.6 Refrainment from accepting gifts, money, or any other privilege from companies in return for facilitating administrative processes.

2.7 Granting rights for production, import, brand registration, goods clearance, and similar activities based on policies of the community and legal procedures.

2.8 Refrainment from allowing political, religious, and social beliefs, race, color, gender, belief, marital status, and family relationships to interfere with decisions

2.9 Freedom from bias and partiality towards a particular company in terms of drug information provided to the public, and considering individual and company privacy rights in declaring drug information

2.10 The Food and Drug Organization should try to inform the involved company(ies) at least one week to 24 hours before they disclose safety information to the public.

## 2. ETHICAL OBLIGATIONS OF THE FOOD AND DRUG ORGANIZATION TOWARDS CONSUMERS

2.1 Establishing qualitative and quantitative standards in accordance with the needs of the community and in line with patient interest regarding the production, import, export, and distribution of drugs, and communicate them to factories and target companies.

2.2 Qualitative and quantitative control over production and import of raw material, and striving to enhance their quality

2.3 After introduction to the market, should there be any report indicating serious side effects, results of investigations must be immediately communicated to physicians and the public, and the drug must be recalled from the market as fast as possible.

2.4 Granting drug production or import permits with close consideration to community needs and enhancing its level of quality by applying specific criteria

2.5 Striving to facilitate consumer access to pharmacy services

2.6 Granting new drug production or import permits with consideration to the quality of the product and community needs with the purpose to advance the pharmaceutical industry of the country

2.7 Regulating the processes of production, packaging, import, and distribution of drugs to avoid damage to the environment

2.8 Close monitoring of the processes of production, packaging, import, and distribution of herbal

medicine and drugs used in traditional medicine in terms of their quality, quantity, and true effectiveness on claimed indications of use

٢.٩ Devising and developing special regulations on the production, import, and distributions for narcotics in order to minimize their abuse

٢.١٠ Preventing the production or import of drugs, raw material, or supplements that are low quality, non-standard, or smuggled, and prosecuting responsible bodies in order to enrich the drug culture of the country

٢.١١ The Food and Drug Organization is mandated to control of the safety and effectiveness of drugs while they are available in the pharmaceutical market of the country.

٢.١٢ This committee is mandated to remove unsafe and ineffective drugs from access in order to protect public health

٢.١٣ The Food and Drug Organization is mandated to develop proper, logical, and ethical criteria to send physicians and researchers to scientific meetings within the country and abroad, and communicate them to companies.

٢.١٤ This organization must examine deceitful advertisements regarding the distribution and sale of drugs (present drugs to be safe and effective using deceit, false advertisement, and without scientific proof), and if such act is substantiated, apply relevant restrictions.

٢.١٥ The Food and Drug Organization must audit its regulations so that relationships between drug manufacturers, importers, and distributors may not be based on unreasonable financial relations (incentives, cash and non-cash), and shall not lead to false competition or reduced quality of drugs.