Introduction

In the case of pharmaceutical care, one of these ends is to benefit patients through the appropriate utilization of pharmaceuticals, using the essential knowledge that should always accompany such clinical intervention. The practitioner should not only be clinically competent, but should also adhere to the law, codes of conduct and ethical standards.

Pharmaceutical care is dependent upon human interactions. These interactions include patients, family members, pharmaceutical care practitioners, other clinicians, support personnel, managers and administrators. These individuals are likely to have different values, beliefs and preferences. Whenever two people with different value systems interact, there is the potential for an ethical problem to develop. Because ethical problems are common in practice it is important that practitioners know how to identify and resolve them when they arise.

Identifying and addressing ethical problems would be easier if they were not so often confused with clinical and legal issues. These three issues "**clinical, legal and ethical**" can be so closely associated that they appear to be the same problem. It will be helpful if the three issues can be separated, when possible, because a successful resolution to each issue is arrived at slightly differently. Each situation requires different knowledge for its recognition and a somewhat different process for its resolution.

Although each patient situation is unique, clinical problems should be identified and resolved first, followed by legal issues, and if an ethical problem remains, it can then be resolved effectively. Thinking in this order will make the identification and resolution of the ethical problem more manageable.

"Ethics" is the study of the rightness or wrongness of human conduct. Also, it is the systematic study of moral choices; it concerns the values that lie behind them and the language used to describe them.

"Ethical decision-making" is the process whereby one recognizes that a problem needs to be overcome or a difficult choice made, identifies the possible courses of actions, chooses one, takes it and then accepts responsibility.

Why do we need a focus on pharmacy ethics?

Generally, there is a view that:

- The law informs you about what you must do or must not do.
- Ethics helps you to decide what you ought to do when the law is silent.

The Law

Pharmacy law consists of rules, regulations, and actions that are promulgated by governments and are binding on its constituents. Law and ethics, while in most cases clearly demarcated, often overlap and sometimes appear contradictory.

Ethical norms

Ethical norms are rules of behavior to be complied with or used to evaluate or direct human conduct. In other words, they are firm guidelines on how we should live.

Normative ethics concerns basic questions such as: what is right and wrong, good or bad. To put this another way, which actions should I perform and which should I avoid? There are important links with what things are considered to be intrinsically valuable.

Morality

The term morality refers to right moral conduct or a moral system, and by 'moral', we generally mean those aspects reflecting the rightness or wrongness of an action or relating to the goodness or badness of human character or behavior. The words 'moral' and 'ethical' are often used as synonyms.

In modern usage, "moral" commonly refers to qualities or descriptions such as right or wrong, good or bad, or is concerned with conformance with behavioral standards – in other words, practical application.

"Ethics" is used in dealing with moral questions from a theoretical point of view, or put more formally; it is the science of morals in human conduct.

Moral intuitions

Moral considerations are to a significant extent subjective, relating to upbringing, cultural background, reflecting personal experiences and feelings or religious teaching and faith.

Moral relativism

What is considered to be wrong in the moral sense undoubtedly can and does sometimes change with time, laying all contemporary opinions open to a charge of moral relativism. In other words, what we believe to be right or wrong now may be judged differently in the future.

Facts and values

Facts and values are often perceived as being polar opposites the one indisputable (facts) and the other (values) much more open to question.

For instance, "facts" or *objective claims* are susceptible to empirical analysis or experimentation. They can be investigated and confirmed. If a factual claim is made, then there are established and approved means of verification which most competent scientists would accept.

By comparison, to claim that it is wrong to lie or steal or to intentionally terminate the life of another human being expresses a *subjective value claim*. Indeed, the claim may not be universally agreed. Even members of the same family can have different views; say on the sanctity of human life, and people across a wide social, cultural or religious spectrum will almost certainly recognize a diversity of values in their daily lives.

Normal values are "close to the sociological notion of norms, rules, habits, expectations and assumptions", while *aspirational values* are reflecting "notions of ideas, goals and visions that are sought rather than assumed".

Pharmacy ethics

Although the term pharmacy ethics is often directly linked with pharmacy law, it has received relatively little attention in the past as a distinct discipline. And while medical ethics has a long history and is often the subject of coverage in the news media, and nursing ethics has become increasingly prominent over the last few decades, pharmacy ethics does not have a well-established independent basis or a substantial literature.

A reason for this may be that pharmacists have been far less likely in the past than other healthcare workers to be directly confronted with situations in which they have to make a primary decision with a significant ethical component.

While they are not regularly primary decision-makers on ethical matters, all pharmacists are members of organizations or are participants in activities where decisions with a moral consideration are made.

Examples of Health Care-Related Ethical Issues

- Abortion
- Assisted reproduction
- Oral contraception
- Emergency contraception
- *Assisted suicide*
- *Euthanasia*
- Confidentiality
- Conscientious objection
- Rationing of health care
- Donation of genetic material
- Research related ethical issues:
    - Animal testing
    - Biologic research
    - Genetic research
    - Informed consent
    - Investigational drugs
- Risk-benefit limitations (e.g., clozapine)
- Substance abuse and dependence
- Performance enhancement (e.g., steroids)
- Pharmacy benefit management
- Promotion of prescription drugs
- Withholding or withdrawal of treatment interventions
    - Cardiopulmonary resuscitation
    - Fluids
    - Intubation and ventilation
    - Nutrition (tube feedings, total parenteral nutrition)
    - Kidney dialysis

Ethical theories and concepts

There are three major theories or rather theoretical concepts that individually have received fairly wide contemporary support and are often cited in ethical discussion.

1- Deontological ethics

Deontology is the study of the nature of duty and obligation. Deontological ethics is essentially a duty-based theory. Within this system, duty-based principles reflecting are considered to be fundamental and mandatory, and take precedence over any consideration of outcome.

As with all ethical theories, but especially in deontological ones, considerable emphasis is given to the importance of respect for the special status of human beings, a respect that should not be ignored and cannot be overridden.

The theories of deontological ethics deal with actions, as they are intrinsically right or wrong regardless of their consequences.
This respect is clearly apparent in the United Nations' Declaration of Human Rights of 1948, where the term dignity is also given prominence: "*Whereas recognition of the inherent dignity and of equal and inalienable rights of all members of the human family is the foundation of freedom, justice and peace in the world*…"

2- Consequentialist and utilitarian ethics

The polar opposites of deontological ethics, but also based on identified principles, are varieties of consequentialist ethics. As the name suggests, the main consideration of consequentialist ethics is instrumental, favoring action that will achieve the best possible consequence or result.
Utilitarian theories are the best way to deal with different medical issues such as medical research and resource allocation
The concept makes clear that it is not the nature of the action but its outcome that is most relevant in ethical behavior. But this raises important issues of just what constitutes the best consequence: how is this to be assessed and, importantly, the best consequence for whom?

3- Virtue ethics

Virtue is the behavior showing high moral standards. An approach to ethical theory that has found favor in recent years in healthcare is virtue ethics. The concept is sometimes referred to as being *aretetic*. (a word derived from *aretê* from the ancient Greek word for virtue)
There is emphasis on the character of the person performing the action rather than on the action itself. It concentrates on the importance of inner character traits like honesty, courage, faithfulness, trustworthiness, and integrity.
Healthcare professionals are expected to demonstrate such characteristics virtues, which can be inculcated in them throughout education and training.

Pharmacy Code of Ethics

The foundation of ethical pharmacy behavior is the premise that the welfare of humanity is the pharmacist's primary consideration. The declaration that *"every pharmacist shall devote himself carefully and diligently to his task so that the sick and suffering are not neglected and no harm is done to them*" was made by a group of pharmacists in 1456. The document containing this statement is considered one of the oldest known ethical commitments made by a group of pharmacists.

The first American pharmacy code of ethics was adopted in 1848 by the Philadelphia College of Pharmacy.

The American Pharmacists Association (APhA), founded in 1852, modeled its first code of ethics after the Philadelphia College of Pharmacy code of ethics. APhA code of ethics was revised in 1922, 1952, 1975, and 1994. The 1994 code of ethics differs significantly from earlier versions in that it provides principles based on "moral obligations and virtues" rather than practice-specific guidelines. The 1994 code for the first time defines the pharmacist-patient relationship as a covenant, implying moral obligations such as compassion, caring, honesty, and integrity.

The profession's ethical principles are further emphasized by the oath of the pharmacist. The 2007 oath that is traditionally taken at the time of graduation from pharmacy school includes the expectation that pharmacists will respect and protect personal and health information and will help to prepare the next generation of pharmacists.

In recent years, several national and international pharmaceutical bodies have promulgated Codes of Ethics and we digress slightly to consider certain factors common to each. The form of these codes varies according to the geographical and legal system of each country. They may be national, as with Great Britain and New Zealand, or federal, applying to a number of states such as in Australia and Canada, or produced by international bodies such as the *Federation Internationale Pharmaceutique* (FIP) and the *Groupement Pharmaceutique de l'Union Européenne* (GPEU). A further variation may be found in France, where the Code of Ethics for pharmacy is part of a general code for all health professionals, namely the *Code de Déontologie des Pharmaciens*, which is part of the French *Code de Santé Publique*.

The 1994 Code of Ethics Pharmacists in USA

PREAMBLE

Pharmacists are health professionals who assist individuals in making the best use of medications. This Code, prepared and supported by pharmacists, is intended to state publicly the principles that form the fundamental basis of the roles and responsibilities of pharmacists.

These principles, based on moral obligations and virtues, are established to guide pharmacists in relationships with patients, health professionals, and society.

PRINCIPLES

I. A pharmacist respects the covenantal relationship between the patient and the pharmacist.

II. A pharmacist promotes the good of every patient in a caring, compassionate, and confidential manner.

III. A pharmacist respects the autonomy and dignity of each patient.

IV. A pharmacist acts with honesty and integrity in professional relationships.

V. A pharmacist maintains professional competence.

VI. A pharmacist respects the values and abilities of colleagues and other health professionals.

VII. A pharmacist serves individual, community, and societal needs.

VIII. A pharmacist seeks justice in the distribution of health resources.

- *Code of Ethics for Pharmacists was adopted by the membership of the American Pharmacists Association in October 27, 1994.*

What About the Iraqi Pharmacists' Code of Ethics?

Physician Code of Ethics

The American Medical Association (AMA) established the first American medical code of ethics in 1847. The code was first revised in 1906 after several decades of discussion. The current code was revised in 2001. It describes the responsibilities of the physician to patients, society, other health care professionals and self and establishes specific standards of conduct.

The Canadian Medical Association (CMA) Code of Ethics first published in 1868. The code is updated every 5-6 years and has a major revision approximately every 20 years. 2004 edition is the most recent.

The World Medical Association (WMA) International Code of Medical Ethics Adopted by the 3rd General Assembly of the World Medical Association, London, England, 1949 and amended in 1968, 1983 and 2006.

Nursing Code of Ethics

In the United States, the Florence Nightingale Pledge was adapted from the Hippocratic Oath in 1893 for the Farrand Training School for Nurses in Detroit, Michigan. The American Nurses Association established the Code of Ethics for Nurses in 1950 to support the ethical obligation of nursing and it has recently been amended to reflect the ever-changing health care environment. The current Code of Ethics for Nurses describes the goals, values, and obligations of the nursing profession. The recent edition was published in 2015 and it will be expired in 27 October 2019.

In 2017, the last edition of Code of Ethics for Registered Nurses was published in Canada. This was the first update to the 2008 Centennial Edition. It is adopted by Canadian Nurses Association.

The Code of Ethics for Nurses in Australia was first published in July 1993. And last revision was in 2002. It is adopted by Nursing and Midwifery Board of Australia and Australian College of Nursing.
From 1 March 2018, the International Council of Nurses Code of ethics for nurses will take effect for all nurses in Australia and the International Confederation of Midwives Code of ethics for midwives will take effect for all midwives in Australia. These documents will replace the Code of ethics for nurses - August 2008 and the Code of ethics for midwives - August 2008.

Hippocratic Oath

The Hippocratic Oath, attributed to the fifth century B.C. Greek physician Hippocrates, is considered the basis for modern medical ethical standards. The oath is found in the Hippocratic corpus, a collection of literature containing case reports, descriptions of disease processes, and medical philosophies generally attributed to Hippocrates. Issues addressed in the oath include patient advocacy, patient confidentiality, professional misconduct, and the need to defer to those with more appropriate training and experience.
There are several modernized versions of the Hippocratic Oath. The newer versions of the Hippocratic Oath differ from the original version in that they typically do not require swearing by any higher authority and make no reference to abortion, euthanasia or sexual behavior.

Oath of a Pharmacist

I promise to devote myself to a lifetime of service to others through the profession of pharmacy. In fulfilling this vow:

- *I will consider the welfare of humanity and relief of suffering my primary concerns.*
- *I will apply my knowledge, experience, and skills to the best of my ability to assure optimal outcomes for my patients.*
- *I will respect and protect all personal and health information entrusted to me.*
- *I will accept the lifelong obligation to improve my professional knowledge and competence.*
- *I will hold myself and my colleagues to the highest principles of our profession's moral, ethical and legal conduct.*
- *I will embrace and advocate changes that improve patient care.*
- *I will utilize my knowledge, skills, experiences, and values to prepare the next generation of pharmacists.*

I take these vows voluntarily with the full realization of the responsibility with which I am entrusted by the public.

Ethical Considerations In Pharmaceutical Care Practice

The most common situations that involved ethical issues could be grouped into two different types:

1. Situations which occur daily during the ***patient/practitioner interaction*** and consist of:
    - Patient confidentiality and privacy issues
    - Conflicts of interest
    - Respect for patient autonomy
    - Duty to warn
    - Patient/practitioner conflicts in values

2. Situations that occur in the ***institutional context*** and involve:
    - Allocation of resources and rationing
    - Personal competency and colleague competency
    - Protection of standards

Patient Confidentiality and Privacy Issues

Pharmaceutical care practitioners deal with patient-specific information that is personal and sensitive, therefore patient confidentiality and privacy must be maintained at all times. This includes all written documents and records, as well as all verbal discussions, which must be held in the strictest of confidence. Patients trust practitioners not to disclose any personal information about them to any person who is not directly involved in their care. This includes the prohibition of practitioners from discussing individual patient cases with friends, family members, or any other clinicians or lay individual without the express permission of the patient.

Conflicts of Interest

Conflict of interest for an individual is defined that an individual has a conflict of interest when a personal, financial or political interest exists that undermines his or her ability to meet or fulfill primary professional, ethical, or legal obligations.

Conflicts of interest can best be identified and dealt with when specific practitioner's roles and relationships and their ethical underpinnings are clearly defined, understood and universally accepted. Within the context of pharmaceutical care, we have argued that the practitioner's primary obligation is to patients and their well-being. Meeting patient's needs comes first, and their best interests are to be sought, upheld and protected at all times.

Example: There is a potential for a conflict of interest if the practitioner is in a position to personally benefit from the selection and use of a particular drug product unless that product is unique and no acceptable alternatives exist. In either case, the practitioner needs to disclose his/her personal interest in that product to the patient.

Self-interest and the interests of employers or institutions should not be placed before those of the suffering. Practitioners must critically examine all patient care decisions to expose any conflict of interest issues that may harm the patient. Personal bias and financial or political interests that affect judgment, reasoning, motivation or behavior should be suppressed by practitioners who put the patient first.

Patient Autonomy

Patients expect practitioners to respect their autonomy. Practitioners must avoid being coercive. All of the information about drug therapies that practitioners share with patients must be accurate and true. Practitioners often need to be persuasive when helping patients decide, but patients must be allowed to make and participate in their own decisions. Patient autonomy is best maintained by negotiating a mutually acceptable care plan.

Practitioners can find themselves feeling strongly that a patient needs some specific form of pharmacotherapy. Health care practitioners often disguise paternalism as behaving in the best interest of the patient. It is difficult to act on someone's behalf if he/she does not want you to do so. However, some would argue that when patients are ill they lose some of their autonomy, and by treating them (acting in their best interest) you have helped them regain some autonomy. In patients who are critically ill, it is often the responsibility of the practitioner to make decisions that are deemed to be in the best interest of the patient.

Duty to Warn

Drugs can save lives, improve health, and prevent illness. However, they can also cause harm. Some of the harm caused by drug therapies is unpredictable, but many of the harmful effects of medications can be expected and are therefore predictable. Practitioners who treat patients with medications have a duty to warn patients of the known risks associated with drug therapies. Patients have the right to expect the pharmacist to provide appropriate warnings of any harmful actions (due to side effect or drug interaction) that the drug regimens may cause.

Conflicts in Value Systems

Patients and practitioners often come from different backgrounds, religions, educational systems and cultures. The practitioner must examine his/her own value system. It is important to understand that each patient can have a different set of values and that in some cases, the patient's way of acting or deciding will be very different from the practitioner's.

Understanding the patient's perspective can be enlightening and empowering in deciding how to manage potential ethical dilemmas. It is your professional responsibility not to put yourself in practice situations where you can anticipate that your personal value system will conflict with your practice obligations.

Allocation of Resources

How decisions are made to allocate resources can generate ethical dilemmas. Resource allocation impacts many patients. Allocation of resources most often involves financial considerations. These decisions are made on a population basis by health care planners and managers. These guidelines are carried out on a patient-by-patient basis by practitioners.

It is the responsibility of individual practitioners to advocate on the patient's behalf to secure the resources necessary to provide the appropriate level of care. Resource-based dilemmas can often place the practitioner at odds with health care managers, administrators or payers. It is the practitioner's duty to argue and support the clinical merits of the case.

Competency

Competency refers not only to the practitioner's grasp of pharmaceutical knowledge, but also adherence to standards and to their protection. The phrase *clinically competent* should refer to a practitioner who is pharmaceutically, legally, culturally and ethically informed and has a commitment to draw upon appropriate available knowledge bases when meeting a patient's needs and resolving problems.

Health care practitioners review and evaluate one another. Allowing a practitioner who is not competent to provide care to patients can create a serious ethical dilemma.
Similarly, each practitioner has the duty to maintain his/her own competency in the knowledge and skills necessary to provide appropriate safe care. In order to be considered competent, a practitioner must recognize the limits of his or her knowledge and inform patients and colleagues.

Protection of standards

All pharmacy professionals contribute to delivering and improving the health, safety and wellbeing of patients and the public. Professionalism and safe and effective practice are central to that role.

Pharmacy professionals must:

1. provide person-centered care
2. work in partnership with others
3. communicate effectively
4. maintain, develop and use their professional knowledge and skills
5. use professional judgement
6. behave in a professional manner
7. respect and maintain the person's confidentiality and privacy
8. speak up when they have concerns or when things go wrong
9. demonstrate leadership

The Practitioner's Responsibilities

Patients' rights:

Every patient has a right:

- To be treated according to his/her unique character.
- To decide and act on his/her own values to fulfill individual life plans.
- To expect complete objective information and the emotional support necessary to act effectively on that information.
- To the control of his/her time and effort alone or through a health care professional.
- To expect whatever benefit is possible in the health care setting and to expect no avoidable harm.
- To expect that agreements established with the health care professionals will be kept.

Basic Professional Behaviors Expected in Practice

Professional behavior	**Ethical principle**
Do the very best you can for every patient	Beneficence
In all cases, do no harm	Non-maleficence
Tell the patient the truth	Veracity
Be fair	Justice
Be loyal	Fidelity
Allow the patient to be the ultimate decision maker	Autonomy/paternalism
Always protect your patient's privacy	Confidentiality

Beneficence

The ethical practitioner will want to do what is best for the patient. While perhaps exceptionally well-informed on pharmacological matters, we have seen that in itself, this does not mean that the practitioner knows best. Clearly, when the centrality of the patient and his/her preferences are considered, deciding what is best under any circumstance involves more than professional opinion and alternatives.

For example, deciding the burdens and benefits of therapeutic protocols cannot be carried out without the involvement of the patient. Patients will decide what risks to take, what benefits they desire, and what burdens they are willing and able to endure.

Non-maleficence

All health care practitioners are familiar with the Hippocratic principle of ***do no harm***. This can be seen as linked to the principle of beneficence. However, while we may all agree that any principles opposed to inflicting harm must be accepted, it is reasonable to suggest that wherever there is risk, there is the potential to harm.

At no time should the pharmaceutical care practitioner aggressively force a treatment on a patient. No matter what justification is offered, whether in the name of pharmaceutical science, clinical evidence or practitioner preference, and the clinician who performs without due regard for the patient's considerations acts maleficently. In this sense, ***the end does not justify the means***.

Veracity

While we endorse the ethical principle of veracity, and believe honesty to be a highly regarded part of character, we also recognize that in practical terms, grounded in the realities of human suffering, individual practitioners are fallible creatures, and often lack the emotional strength necessary to tell the complete truth if they are convinced that it will harm the patient. Emotional strength, conscience and clinical judgment can present barriers to truth telling.

Justice

Justice is an ethical principle "that relates to fair, equitable and appropriate treatment in the light of what is due or owed to persons. The principle of justice recognizes that giving to some may deny receipt to others."

Frequently, patient circumstances raise serious considerations of fairness and justice. Not all patients can afford essential drugs.

In effect, it is reasonable to expect the ethical pharmaceutical care practitioner to make every effort to treat all patients equally and assist those who are legitimately disadvantaged by locating information and programs that will meet their needs. This is not to suggest that all pharmaceutical care practitioners should become social workers, but rather to know the health care system in general and policies in particular and use this information to solve a patient's problems of access to care and pharmaceuticals.

Practitioners will be expected to adhere to the principle of equality in so much as they care for patients as equals regardless of ethnicity, class, gender or sexual preference. Discrimination of any kind is unacceptable, unethical and intolerable.

Fidelity

This is an ethical principle that relates "to the concept of faithfulness and the practice of keeping promises."

Pharmacists are granted authority to practice by a society that regulates competition through licensure and thereby protects the self-interests of the profession. In a real sense, such a social contract provides privileges to an elite group, and in doing so demands accountability.

To be a pharmacist is to make and keep promises to patients. Of course, it can readily be seen that fidelity is related to trust as an essential part of any meaningful therapeutic relationship.

Autonomy

No one is entirely self-governing. For the purpose of ethics discourse, however, the concept of autonomy refers to a patient having the freedom to make choices for him or herself. In this sense, it implies that an individual is free from coercion or threat and can make informed decisions as a free agent.

This does not mean that other individuals play no role in influencing the choices people make, rather, it means that individual choices are respected and subsequent interventions are predicated on respect. This is particularly true when the patient's choices conflict with those of the practitioner. Respect for patients is mandatory. Without it there can be no trust, no therapeutic relationship, and no care.

Paternalism

Paternalism refers to "*the practice of overriding or ignoring preferences of patients to benefit them or enhance their welfare*."
Paternalism represents the judgment that beneficence takes priority over autonomy. There are very few occasions when paternalism should be acted upon.

Pharmaceutical care is committed to informed patient preference. As stated earlier, the pharmacist and the patient form a therapeutic alliance where the patient is given to understand the pharmacist's responsibilities and duties and, most importantly, understands his/her personal responsibilities in relation to those of the pharmacist. In effect, both the practitioner and patient must have a clear understanding of the rules, roles, and responsibilities central to the therapeutic relationship. Without such an understanding there can be no meaningful relationship that produces positive outcomes.

Confidentiality

The trust that is built between practitioner and patient is compromised without the assurance of confidentiality. The duty to protect patient confidentiality emerges from a relationship based upon trust.

As a clinician with clearly defined pharmaceutical care responsibilities, you have a duty, within the context of the therapeutic relationship to protect a patient's personal information from public view.

The expectation of confidentiality is essential to further the free exchange of information between patient and practitioner and should not be taken lightly.

Patients must feel that anything they say, the nature of their disease or illness, the medications they take, or any other matter they regard as private will be respected.

Standards of Professional Performance for Pharmaceutical Care Practitioners

Category	*Standard*
Quality of care	The practitioner evaluates his/her own practice in relation to professional practice standards and relevant statutes and regulations.
Ethics	The practitioner's decisions and actions on behalf of patients are determined in an ethical manner.
Collegiality	The pharmaceutical care practitioner contributes to the professional development of peers, colleagues, students, and others.
Collaboration	The practitioner collaborates with the patient, family and/or care-givers, and health care providers in providing patient care.
Education	The practitioner acquires and maintains current knowledge in pharmacology, pharmacotherapy, and pharmaceutical care practice.
Research	The practitioner routinely uses research findings in practice and contributes to research findings when appropriate.
Resource allocation	The practitioner considers factors related to effectiveness, safety, and cost in planning and delivering patient care.
Allow the patient to be the ultimate decision maker	Autonomy/paternalism
Always protect your patient's privacy	Confidentiality

Human rights and healthcare

Awareness of human rights is being integrated into concepts of consent and the treatment of vulnerable patients; into improved access to healthcare resources for disadvantaged patients and into enhanced respect for patients' privacy, dignity and lifestyles. No health professional should be practicing in modern times without an awareness of human rights.

The following points are the main articles included in human right laws:

- Protection of right to life
- Prohibition of torture
- Right to liberty and security
- Right to a fair trial
- Right to respect for private and family life
- Freedom of thought, conscience and religion
- Right to marry and found a family
- Prohibition of discrimination

Issues at the beginning and end of life

Individual pharmacists often express a variety of views or reservations on the moral implications of beginning of life and end of life interventions. Religious beliefs, socio-cultural background and perhaps the age group of the individual will have a strong bearing on a person's general attitude to many aspects of life and death, and indeed with regard to causes and treatment of disease.

The interventions most relevant to pharmacists are:

- Beginning of life
  - Routine contraception
  - Emergency contraception
  - Termination of pregnancy: non-surgical or therapeutic abortion
  - Fertility treatment
  - Genetic screening
- End of life
  - Assisted dying (*euthanasia*)

Capacity and consent

Consent is now increasingly important where pharmacists, alongside all other health professionals, retain and have access to a wide range of sensitive personal information about patients. A clear understanding of the nature of consent is essential to the confidential management of such information and the securing of consent to disclosure.

Three components of ethically valid consent:

1. The consent must be voluntary
2. The consent must be given by a competent individual
3. The consent must be taken in the light of sufficient information and understanding of that information to enable a decision to be made.

Vulnerable patient groups

Vulnerable patient groups would include children, the elderly, those with impaired learning abilities and the mentally disordered.

✓ **Unconsciousness**

The health professional must decide that intervention is necessary and then take whatever action he or she judges to be in the patient's best interests. This concept has extended to the involvement of relatives, carers and friends in seeking to ascertain what would have been the patient's wishes on a whole variety of matters, such as past and present wishes and feelings or religious or cultural views, had they been capable of expressing them.

✓ **Children**

If the child achieves a sufficient understanding and intelligence to enable him or her to understand fully what is proposed, he or she might give his own consent, and refuse to allow disclosure to the parent.

✓ **Vulnerable Adults**

Pharmacist should empower and protect vulnerable people who are not able to make their own decisions.

Research ethics and clinical trials in therapeutic research

All medicines employed in pharmacy are subjected to two linked phases of activity: discovery and validation.

Clinical trials in human beings have two main functions:

- Demonstrate efficacy
- Identify possible adverse (side) effects.

Clinical trials are undertaken on a phased basis, with increasing numbers:

Phases	**volunteers**	**No.**	**Comments**
Phase I	healthy volunteers	about 20–80	Small-scale study in healthy volunteers to assess pharmacokinetics, safe or tolerable dosage and route of administration
Phase II	patients	100–300	Suffering from relevant disease to provide evidence of effective dosage and safety
Phase III	patients	1000–3000	To establish formal safety, effectiveness and comparability
Phase IV	Real patients	unlimited > 3000	Post-marketing studies in patients to identify low-level adverse effects.

Various aspects of randomized clinical trials have an ethical dimension. In participating in clinical trials, both healthy volunteers and patients are entitled not to be harmed and for respect to be shown for their autonomy. A duty of care to prevent harm is generally taken care of by:

A. Ensuring the adequacy of pretrial safety data
B. Appropriate supervision and monitoring during and if necessary following the trial.

The most important issues concern personal ***autonomy*** and ***consent***. This means being sure that:

- The patient is fully aware of the main aspects of the study, including an assessment of possible personal benefits or risks
- The patient has a clear understanding that they may receive an inactive placebo
- The patient does not feel obliged to participate for any reason and knows that he/she may withdraw at any stage without being penalized.

A capable person gives informed consent to take part in a clinical trial only if his decision:

A. is given freely after that person is informed of the nature, significance, implications and risks of the trial
B. either:
    i. is evidenced in writing, dated and signed, or otherwise marked, by that person so as to indicate his consent, or
    ii. if the person is unable to sign or to mark a document so as to indicate consent, is given orally in the presence of at least one witness and recorded in writing.

Approval of Research proposals

Research is described in a formal proposal or protocol which indicates an objective and the procedure to reach that objective. ***Declaration of Helsinki*** stipulates that every proposal for medical research on human subjects must be reviewed and approved by an independent ethics committee before it can proceed.
The ethics committee of clinical research is the institutional entity at the local institution that is responsible for protecting the rights of human. This committee is composed of members with or without a background in health care and research. At least one clinical pharmacist must be a member of the ethics committee.

Funding in research

Medical research is a well-funded enterprise, and physicians are sometimes offered considerable rewards for participating. These can include cash payments for enrolling research subjects, equipment such as computers to transmit the research data, invitations to conferences to discuss the research findings, and co-authorship of publications on the results of the research. The physician's interest in obtaining these benefits can sometimes conflict with the duty to provide the patient with the best available treatment. It can also conflict with the right of the patient to receive all the necessary information to make a fully informed decision whether or not to participate in a research study.

Researchers with conflict of interest (as occur in funded research) often report positive results with a high statistical significance, implying that readers can trust the efficacy or safety of the drug in question. In addition, privately funded studies rarely report negative findings. If researchers are influenced financially to manipulate experimental data, doctors and patients run the risk of not finding out the real negatives of a drug until it has been used on patients, often on a large scale.

Payment to volunteers for participation in drug trials is common and usually can be subdivided into two types, reimbursement for expenses incurred incidentally and wage payments. Reimbursement might cover expenses such as transportation costs, costs incurred by participation (e.g., extra blood sampling, new drugs or devices being used), and lost work time. Wage payments involve remuneration for services provided in serving as a research subject.

Ethics and ethical issues in case of funded researches:

1. The patient should be informed not only about the research but also about the source of money and about payment.
2. If a researcher may be benefited financially from enrolling patients in research, this must be balanced against patient benefit. Ethically the researcher must focus on beneficence and non-maleficence to the patient.

Placebo

Commonly ethics committees have reservations on the use of a placebo as it is seems to be very unethical to give subjects with the disease condition a placebo. So placebo will only be used if ethically acceptable for example if the new treatment is given in addition to the existing treatment, a placebo can be used to mask whether the participant is receiving the new treatment and the existing treatment, or just the existing treatment.

Placebo controls can be justified if the trial is conducted in an area that falls within one of four broad categories:

1. Conditions for which no standard therapy exists at all
2. Conditions for which standard therapy has been shown to be no better than placebo
3. Conditions for which standard therapy has been called into question by new evidence, creating doubt concerning its presumed net therapeutic advantage
4. Conditions for which validated optimum treatment is not made freely available to patients because of cost constraints or other considerations (e.g., physical location of treatment centers).

To conclude that the drug is effective by research it must provide clinical significance and not only statistical significance.

Use of animals in research

There are two main points of criticism of the use of animals for drug testing.
1. The use of animals for such purposes is morally wrong. (~~The lives of animals are considered to be of less value than those of human beings~~).
2. Using animals to try to predict the behavior of drugs in human beings is scientifically invalid.

A conclusion by an international committee was: "it is morally acceptable for human beings to use other animals, but that it is morally wrong to cause them unnecessary or avoidable suffering".

Essential medicines

The World Health Organization (WHO) promotes universal and equitable access to basic health services and essential medicines. It has been producing a list of 'essential drugs' since 1977. The list is updated biennially. The core list presents a list of minimum medicinal needs for a basic healthcare 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.

In Iraq, Ministry of Health issues National List (for all approved medications in Iraq) and Essential List for medication that are to be used in the government sector.

Orphan diseases, orphan drugs

The term orphan disease (or rare disease) is used to describe those ailments of a chronic or life-threatening nature that are so rare that drug development is not commercially viable using the usual criteria. In Europe, the term is applied to indications with an incidence of no more than 5 in 10000 persons.
There are a lot of problems that confront the patients and their families that finally lead to marginalization and exclusion of patients affected by these diseases from the health programs, even in wealthy countries.

Pharmacogenetics

Pharmacogenetics relates genetic constitution to variable drug response and may eventually provide the basis for optimizing individual treatment with some drugs. More predictable efficacy with fewer side effects would represent a significant improvement in patient care, consistent with the principles of beneficence and non-maleficence.

Genetic screening and genetic knowledge

Medical application of genetic testing is mainly two-fold:

- to identify the presence of genes that may predispose to certain monogenetic diseases in:
    a) children and adults or
    b) embryo, fetus or the newborn,
- to identify genes that have a major influence on drug metabolism.

Life assurance companies may at some time wish to take a client's genetic data into account either by refusing to insure those considered being at high risk or by loading the premium.

Moral concerns broadly relate to:

a) Considerations of privacy, consent and confidentiality
b) Embryo selection.

For consent to be valid, it must be given voluntarily by an appropriately informed person who has the capacity to agree to the activity in question. Adults are competent to consent if they can:

- Understand the nature and purpose of the proposed procedure
- Understand and retain information relevant to the decision
- Weigh the necessary information to arrive at a choice

Reproductive opportunities

Broader and more familiar ethical concerns relate to embryo screening and sex selection; with occasional talk of "designer babies" or "eugenics".

Embryo screening by tissue typing to produce so-called "saviour siblings" is now permitted in some countries. This enables parents to proceed to full pregnancy when and if an embryo free from a serious genetic disorder is successfully tissue matched with a sick sibling.

In the United Kingdom, the *Human Fertilisation and Embryology Authority* (HFEA) has ruled that it is lawful to use modern reproductive techniques to create a savior sibling.

In Australia, use of preimplantation genetic diagnosis (PGD) for human leukocyte antigen (HLA) typing is reviewed by the *Infertility Treatment Authority* on a case-by-case basis.

The role of the pharmacist

The consultancy agreed that contemporary and future pharmacists must possess specific knowledge attitudes, skills and behaviors in support of their roles. WHO summarized these roles in "**the seven-star pharmacist**:"

1. Care-giver

The pharmacist provides caring services. Whether these services are clinical, analytical, technological or regulatory, the pharmacist must be comfortable interacting with individuals and populations. The pharmacist must view his or her practice as integrated and continuous with those of the health care system and other pharmacists. Services must be of the highest quality.

2. Decision-maker

The appropriate, efficacious and cost effective use of resources (e.g., personnel, medicines, chemicals, equipment, procedures, practices) should be at the foundation of the pharmacist's work. Achieving this goal requires the ability to evaluate, synthesize and decide upon the most appropriate course of action.

3. Communicator

The pharmacist is in an ideal position between physician and patient. As such, 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.

4. Leader

Whether the pharmacist finds him/herself in multidisciplinary (e.g., team) caring situations or in areas where other health care providers are in short supply or non-existent, he/she is obligated to assume a leadership position in the overall welfare of the community. Leadership involves compassion and empathy as well as the ability to make decisions, communicate, and manage effectively.

5. Manager

The pharmacist must effectively manage resources (human, physical and fiscal) and information; he or she must also be comfortable being managed by others, whether an employer or the manager/leader of a health care team. More and more, information and its related technology will provide challenges to the pharmacist as he/she assumes greater responsibility for sharing information about medicines and related products.

6. Life-long-learner

It is no longer possible to learn all one must learn in college in order to practice a 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 learn.

7. Teacher

The pharmacist has a responsibility to assist with the education and training of future generations of pharmacists. 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.

– *An addendum to the seven-star pharmacist concept has resulted in the inclusion of two new criteria, thereby giving rise to the 'Nine-star pharmacist'. In addition to the seven roles, the inclusion of pharmacist as a researcher and an entrepreneur is quite significant.*

8. Researcher

Research is not just for academicians. A great deal of research takes place at grass roots level. Research findings can impact on all sectors of the pharmacy profession. A culture change is needed whereby pharmacists see research as a core part of their normal daily practice. There is a need for more practice research to help the profession meet its aspirations. Pharmacists need help and advice about how to get involved.

9. **Pharmapreneur** or **entrepreneur**

An entrepreneur is 'a person who organizes and operates a business or businesses, taking on greater than normal financial risks in order to do so'.
Entrepreneurs are usually viewed as individuals who take substantial risks to go out and start new companies.

The concept of 'Pharmapreneur' is still in its infancy because unfortunately, the mindset of almost all pharmacists is that their profession extends to only drug dispensing and its associated activities within a hospital or clinical setting. Most pharmacists go to work for entities that are already established, such as a community pharmacy or hospital. Such positions are generally considered safe, as they promise a steady paycheck and continued employment. For that reason, entrepreneurship is not commonly listed among a pharmacist's skill sets.

Ethics and advertisement and promotion of prescription drugs

Advertisement is an art used to familiarize the public with product by informing its description, use, price and its superiority over other brands. It makes potential buyers aware of new products that are available in the market.

Promotion refers to all informational and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal drugs. It is a part of advertisement.
It is well known that increasing drug promotion will increases drug sells, and it is more likely that the relationship between promotion and sales is not a 1 way link but it is a 2 way negative feedback loop, more promotion lead to higher sales which lead to more promotion.

Health care professionals question the ethics of accepting gifts from drug companies. Gifts ranging from low cost items such as pens, notepads, clothing, textbooks and meals to high-cost gifts such as all-expense-paid trips to luxury resorts and cash gifts used to be common.

Pharmacists attending national pharmacy association meetings often attended industry-sponsored continuing education presentations, receptions and parties and collected bags of gifts from pharmaceutical industry exhibitors.

The ethical issues are complex and grow out of the unique relationship between the pharmaceutical industry and health care professionals. Unlike other types of advertising, pharmaceutical advertising targets health care professionals, who influence drug selection, and not patients, the ultimate consumers of the products. Acceptance of these gifts carries ethical implications, no matter the monetary value of the gift.

The ethical implications of accepting gifts from the pharmaceutical industry involve issues of justness and obligations. The cost of pharmaceutical gifts and other forms of advertising is included in the price of medications.

Therefore, some argue that spending patients' money without their knowledge or consent and without direct benefit is unjust. Gift giving also implies obligations on the part of the recipient. The obligations may be subtle, but even the appearance of an obligation may alter society's trust in the profession.

Common practices of the past, such as sponsoring dinner at a local restaurant, paying for fuel or entertainments or giving gifts such as toys or mugs imprinted with a drug name, are no longer acceptable. The code allows companies to offer gifts that are primarily for patient education (e.g., anatomic models, educational posters) if the gift is not of substantial value and does not have value beyond the health care professional's professional responsibilities. Companies can provide modest meals with presentations if the presentation is at the health care professional's office or hospital.

Objectives of Advertisement:

1. To create a demand for new products
2. To maintain the existing demand of the product
3. To enlarge the market for the product
4. To increase sales
5. To educate people about the application and use of product
6. To improve goodwill of the manufacturer
7. To help manufacturer in acing competition
8. To warn the customers about imitation
9. To establish direct relation between company and customer

Medias for advertisement

1. Print media (catalogues, newspapers, magazines, pamphlets, and journals)
2. Audio-advertisement (Radio)
3. Audiovisual media (TV, CDs, etc.)
4. Outdoor advertisement (posters, cards, wall writing, road painting, banners)
5. Mail advertisement (to physicians, customer or retailers)
6. Personal contact (sales representatives , medical representatives)
7. Window display

WHO ethical and lawful drug promotion

Claims concerning medicinal drugs should be:

- Reliable
- Accurate
- Truthful
- Informative
- Balanced
- Up-to-date
- Capable of substantiation and in good taste.
- They should not contain misleading or unverifiable statements or omissions likely to induce medically unjustifiable drug use or to give rise to undue risks.
- The word "safe" should only be used if properly qualified.
- Comparison of products should be factual, fair and capable of substantiation.

General principles of ethical drug advertisement

1. No person may issue an advertisement for a relevant medicinal product unless that product has a marketing authorization.
2. No person shall issue an advertisement relating to a relevant medicinal product unless that advertisement:
    a. Complies with the particulars listed in the Summary of Product Characteristics, and
    b. Encourages the rational use of that product by presenting it objectively and without exaggerating its properties
3. No person shall issue a misleading advertisement relating to a relevant medicinal product (misleading advertisement is not acceptable)
4. No person shall issue an advertisement which is likely to lead to the use of a relevant medicinal product or substance or article for the purpose of inducing an abortion in women. (Advertisement about drugs that induce abortion is not acceptable)

Tactics for drug marketing and promotion

Pharmaceutical industry's marketing tactics reveals the extent of their influence on patient care and medical research. These tactics can be arranged into five categories according to the potential for harm to patients (from least to most harmful):

A. Physicians-targeted promotions
B. Direct-to-consumer advertising
C. Unethical recruitment of physicians
D. Researchers' conflicts of interest
E. Data manipulation in clinical trials

A. Physicians-targeted promotions

The majority of Big Pharma's marketing budget is targeted at doctors and others with prescribing power, who are effectively the gatekeepers to drug sales.

Advertisement to physicians must include essential information and contains the following particulars:

1. the license number of the product.
2. the name and address of the marketing authorization holder which relates to the product or the business name and address of his/her business that is responsible for its sale or supply.
3. the classification of the product, i.e. *prescription only, pharmacy only, or general sale list.*
4. the name of the product and a list of active ingredients
5. the indications as within the terms of the license.
6. Information about drug side effects, precautions and relevant contra-indications.
7. Information relating to the dosage and method of use relevant to the indications shown. The method of administration should also be shown where this is not obvious.
8. a warning is required to be included.
9. the cost of either a specified package of the product, or a specified quantity or recommended daily dose, calculated by reference to any specified package of the product, except that the cost.

Doctor-targeted promotion takes a variety of forms:

1. Gifts, such as free samples, small stationery, travel to conferences and educational events, and cash (cash is unethical).
2. Sponsorship of conferences and educational events.
3. The use of key opinion leaders (KOLs) – i.e. senior clinicians and medical educators as speakers at learned conferences.
4. Funding of medical journals through advertising. Pharmaceutical companies use medical journals to advertise their products, and frequently advertising revenue is the only source of funding of these journals, which are often sent free to doctors.

Free samples

The purpose of free sample is for product recall. These samples are sometimes used to initiate treatment for a new patient or, in some cases, to provide medication for a patient who cannot afford to buy it. Ethical questions are always being asked about whether it is ethical to give away free samples or to give medicines for free to the customers.

Although free samples are not intended as gifts to physicians, but may in fact be used in this way, additionally some physicians using free samples un ethically for their personal or family usage.

For free samples to be ethical and lawful, a person may supply a sample only:

1. To a person qualified to prescribe medicinal products;
2. The sample should adhere to the following:
   A. The sample is supplied on an exceptional basis only.
   B. A limited number only of samples of each product may be supplied in one year to one recipient.
   C. Samples supplied may only be in response to a written request, signed and dated from the recipient.
   D. Suppliers of samples must maintain an adequate system of control and accountability.
   E. Every sample shall be no bigger than the smallest presentation available for sale.
   F. Every sample must be marked '***free medical sample – not for resale'*** or bear a similar description.

B. Direct to consumer advertisement

Heavy direct-to-consumer (DTC) advertising strongly correlates with increased sales for the promoted drugs but, in terms of both money and health, may not be in the best interest of patients.

There are essentially two categories of drugs:

- self-medication or over the counter (OTC) drugs, and
- prescription drugs - sometimes referred to as ethical drugs.

OTC drugs are promoted directly to consumers as well as physicians and other healthcare professionals like analgesics and antihistamines however these OTC drugs may vary between one country to another. In the European Union only OTC drugs are promoted directly to consumers.

In the United States and New Zeeland all drugs may be promoted to consumers, but in practice direct to consumer advertising focuses on OTC and common-ailment targeted prescription drugs.

In Iraq countries, there is no any limitation to the type of drug that advertised to consumers.

Types of Direct to consumer advertisement (DTCA)

1. ***Disease awareness advertisements*** do not name specific drugs and are used when only one drug is available to treat the disease outlined. Possible users are encouraged to consider whether they recognize symptoms described and, if so, to contact their doctor.
2. Reminder advertisement or brand awareness advertisements state the drug's name, but do not outline the condition treated. These promotions may maintain the salience of a well-known brand and complement concurrent print campaigns.
3. The most common type of advertising is full brand advertising, which provides details of the drug's name and the condition treated. These advertisements must satisfy the regulatory requirements per country, such as FDA's 'fair balance' criterion or meet the New Zealand advertising code.

DTCA advantages for patients:

1. Alerts patients to new medical products
2. DTCA may make consumers better informed

3. Consumers are enabled, through DTCA, to better understand the market for drugs and the therapeutic options available to them.
4. Consumers can engage in more equitable relationships with health care providers and become partners in their own health care as a result of DTCA which improve patient compliance.
5. Enables earlier diagnosis of conditions and improve treatment regimens

Disadvantage with DTCA

1. Emerging evidence suggests potential end-users with lower literacy levels are less likely to recall risk information than benefit information, thus any knowledge that develops may be unbalanced.
2. Because of consumers' limited knowledge, critics have claimed that benefit-oriented advertising leads to overestimation of efficacy and suitability, and prompts requests based on hope and emotion, neither of which provides a rational basis for prescribing.
3. There is little evidence that DTC promotes more informed discussions, although it may prompt patients to raise issues with their doctor.
4. There is some evidence that patients insist on receiving a prescription for a particular drug, although there is less evidence of 'doctor-shopping', where patients search for a physician who will prescribe a drug.
5. Experimental studies suggest doctors who accede to patients' requests may do so against their better judgment.
6. DTCA may cultivate the belief that there is a pill for every ill and contribute to medicalization of trivial ailments, leading to an even more ''overmedicated'' society.
7. DTCA highly affect less educated people who are readily accept information from DTCA.

C. Unethical recruitment of physicians

Another problem lies in the pharmaceutical industry's public relations firms recruiting physicians to endorse the company's clinical studies.

Example: A completed review paper which was ready to present at upcoming conference in Canada was done by unknown person but for convenience a famous doctor name appeared as a sole author, even he had never seen a single word of it before, the doctor refused such thing but the paper still appear in the conference under the name of other doctor, this real case occur and it is ethically unacceptable and it is not an isolated case.

If that were to happen and more physicians were to take up the offer, then the reputation of medical professionals and the reliability of medical information would be placed at substantial risk.

D. Data manipulation in drug advertisement

Evidence suggests that pharmaceutical companies manipulate clinical data to prevent negative results from reaching the public. Companies may pressure investigators not to submit negative results in funded researches.

Some Major companies funded trials have been published in multiple papers that make the results to appear as separate studies (*Misleading facts*).

Data manipulation may be not disclosing that the research is funded by drug company. This way mislead readers about absence of bias to trust the study results.

The greatest harm that could come from this marketing practice is the reporting of unreliable data, either because of researchers' conflict of interests or the manipulation of data; ethical doctors cannot make sound judgments about the most effective treatments for their patients if the information that they receive is skewed. If this trend continue, patients could end up suffering from unreliable or even dangerous treatments and drug therapies.

E. Researchers' conflict of interest (COI) for researches funded by pharmaceutical companies

Privately funded studies rarely report negative findings. These data suggest that either authors with COI have a better eye for research with positive outcomes or are predisposed to find positive outcomes because of the vested interests they hold. If researchers are influenced financially to manipulate experimental data, doctors and patients run the risk of not finding out the real negatives of a drug until it has been used on patients, often on a large scale.

Prohibition of certain material in advertisements

No person shall issue an advertisement relating to a relevant medicinal product which contains any material which:

1. gives the impression that a medical consultation or surgical operation is unnecessary, in particular by offering a telephone number.
2. suggests that the effects of taking the medicinal product are guaranteed, are unaccompanied by side effects or are better than, or equivalent to, those of another identifiable treatment or medicinal product.
3. suggests that health can be enhanced by taking the medicinal product.
4. suggests that health could be affected by not taking the product.
5. is directed exclusively or principally at children.
6. refers to a recommendation by scientists, health professionals or persons who are neither of the foregoing but who, because of their celebrity, could encourage the consumption of medicinal products.
7. suggests that the medicinal product is a foodstuff, cosmetic or other consumer product.
8. suggests that the safety and efficacy of the medicinal product is due to the fact that it is natural.
9. might, by a description or detailed representation of a case history, lead to erroneous self-diagnosis.
10. refers, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of a medicinal product on the human body or parts.

IFPMA Guiding Principles on Ethical Conduct and Promotion

The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) member companies engage in medical and biopharmaceutical research in order to benefit patients and support high-quality patient care. Pharmaceutical companies, represented by IFPMA, promote, sell and distribute their products in an ethical manner and in accordance with all the rules and regulations for medicines and healthcare.

The following Guiding Principles set out basic standards to inform the 2012 IFPMA Code of Practice:

1. The healthcare and well-being of patients are the first priority for pharmaceutical companies.
2. Pharmaceutical companies will conform to high standards of quality, safety and efficacy as determined by regulatory authorities.
3. Pharmaceutical companies' interactions with stakeholders must at all times be ethical, appropriate and professional. Nothing should be offered or provided by a company in a manner or on conditions that would have an inappropriate influence.
4. Pharmaceutical companies are responsible for providing accurate, balanced and scientifically valid data on products.
5. Promotion must be ethical, accurate, balanced and must not be misleading. Information in promotional materials must support proper assessment of the risks and benefits of the product and its appropriate use.
6. Pharmaceutical companies will respect the privacy and personal information of patients.
7. All clinical trials and scientific research sponsored or supported by companies will be conducted with the intent to develop knowledge that will benefit patients and advance science and medicine. Pharmaceutical companies are committed to the transparency of industry sponsored clinical trials in patients.
8. Pharmaceutical companies should adhere to both the spirit and the letter of applicable industry codes. To achieve this, pharmaceutical companies will ensure that all relevant personnel are appropriately trained.

Global availability of medicines and developing countries

'*Big Pharma'* has an obligation (if any) to make products available at a price locally affordable in developing countries.

The wider the distribution, the greater are potential sales and profits. But most developing counties are unable to afford to pay Western market prices for their medicines. Some pharmaceutical companies do charge significantly lower prices in some of these markets, presumably a lower profit margin can be sustained and there is net marginal value.

In an ideal world, pharmaceutical manufacturers would pursue price discrimination, setting relatively high prices for their patented products to recover R&D investments in the most affluent nations while selling drugs at only a modest markup above marginal production and distribution cost in nations with weak ability to pay.

Advertisements for traditional herbal medicinal products

No person may issue an advertisement for such products that are marketed in the UK under a traditional herbal registration unless it contains the statement:

"*Traditional herbal medicinal product for use in', followed by a statement of one or more therapeutic indications for the product consistent with the terms of the traditional herbal registration for that product, followed by 'exclusively based on long standing use*".

While in the USA, any herbal or supplementation products should be labeled with:

"This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

or:

"These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."