



Ethical Issues in Pharmacy Practice: Run by Ethics Not by Rules

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Received: 10-04-2023; Revised: 20-06-2023; Accepted: 26-06-2023; Published on: 15-07-2023.

ABSTRACT

The term "ethics" refers to "the rules by which a profession governs behavior and establishes standards for all its members." Ethics is a subject that teaches us how to control a profession and uphold its moral standards. All medical professionals and individuals who sell drugs around the world rely on pharmacists for advice on medications. Of all industries, the pharmaceutical sector is the one that is most strictly regulated. We can categorically state that this industry and profession depend on a code of ethics the most in their day-to-day operations. The primary motivator for ethical behavior in a pharmacist is professionalism. The code of ethics for pharmacists may not be a universally accepted standard, but each country will have its own set of rules. The goal of the pharmacist code of ethics is to guarantee that consumers are receiving the best possible medication with guaranteed efficacy and safety. The code of pharmaceutical ethics is a set of moral guidelines that pharmacists must abide by when dealing with patients, the general public, their fellow pharmacists, and professionals in the medical field. In terms of their conduct, behavior, and character, pharmacists are bound by the moral principles of pharmaceutical ethics. Pharmaceutical ethics are optional, whereas pharmaceutical law is required. As a result, the pharmacy profession has a strong commitment to providing selfless service and making sacrifices for the good of the underprivileged community.

Keywords: Ethics, Safety, Efficacy, Fellow pharmacists, Pharmaceutical, Pharmaceutical legislation.

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DOI:

10.47583/ijpsrr.2023.v81i01.007



DOI link: <http://dx.doi.org/10.47583/ijpsrr.2023.v81i01.007>

INTRODUCTION

A) Ethical issues in clinical pharmacy practice: -

1. Patient pharmaceutical care: -

Pharmaceutical care is the current standard of practice in pharmacy, where pharmacists are in charge of drug therapy to achieve the best results and improve a patient's quality of life.¹

Patient autonomy, a duty to warn, patient confidentiality and privacy, and competence in selecting the best medication to be purchased are among the ethical concerns in pharmaceutical care practice.²

The patient's right to information and the doctor's ethical obligation to keep things confidential put pharmacists in a difficult position all the time. In the case of a doctor prescribing a cancer drug, for instance, the doctor may not want the patient to be informed of the side effects as this may result in patient noncompliance. This is a good example of omitting to disclose the side effects of a drug. It would be unethical for a pharmacist to advise a patient directly contrary to a doctor's instruction without first informing the doctor concerned.³⁻⁸

2. Interaction with another medical professional: -

To provide advice on the most recent medications, drug substitutions, drug costs, and anything else relating to drugs or associated devices, pharmacists in clinical practice must collaborate with nurses, doctors, and other medical professionals. Often, pharmacists collaborate with other medical specialists to enhance a patient's treatment rather than working directly with the patient. However, when they travel with doctors and nurses on ward rounds, pharmacists have the chance to see patients. This will be one of the moral dilemmas where the pharmacist is there to help the other professionals but not to comment on their shortcomings in the therapy.⁹⁻¹²

B) Ethical Issues in the manufacturing of pharmaceutical products: -

1. Quality assurance in pharmaceutical manufacturing: -

A system of actions known as quality assurance aims to guarantee, with a high degree of certainty, that a product is fit for its intended use. Ethics are relevant to quality assurance because those involved work to achieve quality-level objectives by taking actions, which helps with quality assurance.¹³⁻¹⁵

Quality control, production, distribution, and inspections are the four main divisions of pharmaceutical quality assurance. Standards and guidelines have been created to supervise the steps taken to achieve quality to support quality assurance. For the production, testing, and distribution of pharmaceuticals, quality assurance will have guidelines. The documents include those on good



manufacturing practices, regulatory approval of pharmaceuticals, prequalification of laboratories, supply agencies, and quality control testing. To truly incorporate quality into pharmaceutical products, quality assurance requires high ethical standards from a pharmacist.^{16,17}

2. Good manufacturing practice: -

The production and testing of pharmaceutical dosage forms or drugs are covered by Good Manufacturing Practice (GMP), which is a component of a quality system. The aspects of production and testing that can affect a product's quality are described. GMP makes sure that quality is ingrained in the product from the very beginning, as opposed to just testing for it at the very end of the production process. GMP addresses both production and quality control (QC), where QC is a series of procedures to evaluate the acceptability of raw materials, processed materials, finished product, and packaging material. If a batch of the product has a defect, the GMP organization's pharmacist should make sure that a system is in place to remove it from sale or supply. Additionally, pharmacists must see to it that customer complaints about marketed products are investigated, the root causes of quality defects are determined, and the proper remedial action is taken for the defective products as well as to stop the defect from recurring.^{1,18}

Pharmacists must put corrective and preventive measures in place to ensure that errors are fixed and do not recur in the future.^{2,19}

Regarding GMP, a pharmacist is an essential staff. A professional and someone with high integrity is required for this important position. Pharmacists should follow the code of ethics in GMP facilities because they are professionals who are subject to regulation by professional bodies.^{3,20,21}

3. Good storage practice and good distribution practice: -

Insufficient control over a variety of activities that take place during the storage and distribution process can have an impact on the quality of pharmaceutical products. The distribution and storage guidelines will help to guarantee the efficacy and integrity of pharmaceutical products in all facets of distribution and storage. Every action taken during the storage and distribution of pharmaceutical products should follow the GMP, GSP, and GDP tenets to maintain quality, safety, and efficacy. Beginning at the manufacturing facility and continuing through the point of supply to healthcare facilities like private pharmacies, hospitals, and clinics for patient supply, everyone involved in any aspect of the storage and distribution of pharmaceutical products is ethically responsible.¹

The cold chain system used in the handling and storage of certain classes of pharmaceuticals that need to be refrigerated, such as vaccines, is a significant issue for GSP and GDP. A cold chain is a supply chain idea that places a strong emphasis on temperature control, to ensure that the low-temperature chain is kept intact under a sequence

of storage and distribution activities by maintaining a specific temperature range. It is used in the pharmaceutical industry to extend the shelf life of products that are temperature-sensitive, such as vaccines.²²

To ensure the effectiveness and safety of the product, those who manage pharmaceuticals that require cold chains must be extremely ethical. Reinstalling a product with a new tag when the product's original tag indicated that the cold chain had been broken can constitute a serious ethical breach.³

4. Ethics of pharmacists in handling product complaints and product recalls: -

The pharmacist should consider other batches when a product defect is found or suspected to exist in one batch to see if they are also impacted. The pharmacist must act right away to recall the product if the flaw poses a serious risk to life, whether during regular business hours or not. Pharmacy professionals should always be ready for product safety alerts, where products may not be meeting safety requirements. Pharmacists should assume responsibility for disseminating the safety alert via all available mass communication channels, such as newspapers, radio, and television, when there is a risk of significant hazard to consumers from a product that has been distributed on the market. To remove the flawed product from sale or use, quick action must be taken under established procedures. The pharmacist must set up a system to quickly and effectively remove products that are known or suspected to be defective from the market. When deciding what to do with the recalled products, the pharmacist must act ethically.¹

If it complies with the necessary standards and requirements, the recalled product may be reworked. If there is any question about the product's identity, safety, or quality, it should be destroyed.²

The safety of people must always come first in all of the decisions that the pharmacist makes; nothing else, not even financial considerations, should take precedence.³

C] Ethical issues on wholesale, supply, import, and export of drugs: -

The actions on drug distribution that are governed by permits and licenses include wholesale, supply, import, and export. Drugs can be diverted to illegal channels for misuse, drugs can be counterfeited, and patient safety is always at risk. Pharmacists trusted with these permits or licenses must demonstrate a high level of ethics. For groups of drugs that are susceptible to abuse, the ethical need in this matter is crucial. Pharmacists are trusted as guardians of these highly abusive drugs, and there is a high tendency for them to abuse their position because the sales of these drugs can be very lucrative for them. Dangerous drugs like morphine, fentanyl, or pethidine as well as psychotropic substances like diazepam or



barbiturates and their derivatives need to be dealt with with a high level of ethics.¹

The majority of countries around the world are UN members and members of the International Narcotic Control Board (INCB) (Vienna). According to the INCB, both the exporting and importing countries must obtain authorization for the import and export of harmful drugs or psychotropic substances by following the rules established by the INCB. The competent authority of the importing nation will grant the pharmacist import authorization. The competent authority of the exporting country will grant the exporter permission to export the product after receiving a copy of the import authorization from the importing country's competent authority. A pharmacist would be unethical if they did not adhere to the INCB's import and export requirements for such drugs.²

Objective:

We sought to examine and assess the ethical issues surrounding pharmacy practice in the community, industries, and supplying pharmacies in this paper.

CONCLUSION

Pharmacy practice has changed over time, and there is an evolution taking place in the area of pharmaceutical ethics that affects the pharmacist personally and the pharmaceutical company as a corporate entity. Pharmaceutical innovation and technological advancement have shaped the pharmaceutical industry, pharmacists, and the need for strong ethics to be ingrained into each pharmacist as an individual. This will form a pharmaceutical organization with high ethical standards. Pharmacy ethics as a whole must be responsive to a constantly changing environment.

Compliance with Ethical Standards:

Conflict of Interest: The authors declare that they have no conflict of interest.

Ethical approval: This article does not contain any studies with animals performed by any of the authors.

Competing interests: The authors declare that they have no competing interests.

Data Availability Statement: The data used to support the findings of this study are included within the article.

Abbreviations:

GMP	Good Manufacturing Practice
QC	Quality Control
GSP	Good Storage Practice
GDS	Good Distribution Practice
INCB	International Narcotic Control Board

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Source of Support: The author(s) received no financial support for the research, authorship, and/or publication of this article.

Conflict of Interest: The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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