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Ethics in Pharmaceutical Issues

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1. Introduction

Pharmacists are the researchers, developers, producers, people who are trusted to give advice on drugs to all health professionals and persons who market drugs in the whole world. The pharmaceutical industry is the most heavily regulated of all industries. Clearly we can say that this profession and this industry is the most heavily reliant on a code of ethics in its everyday practice.

A music writer is a professional in his own personal way; another professional, a musician, can play his music but he cannot write in the way that the writer did. In a similar manner, a doctor knows how to use a medicine but he cannot produce the medicine. This task is undertaken by another professional, the pharmacist. Pharmacists dispense prescription drug products and provide patient information services to consumers in hospitals, nursing homes, retail pharmacy departments and home care settings. Pharmacists consult directly with patients, or with their caregivers, explaining the proper use and storage of drug products and providing information on contraindications of drugs.

Generally, dictionaries define ethics as the issues related to the general nature of morals and of the specific moral choices to be made by a person. In other words, ethics are derived from the moral philosophy of a person. Personal philosophy makes a significant part of any discussion of ethics. Ethics can be influenced by one's family values, educational background, social learning, professional activities, religious beliefs, and individual needs. For a pharmacist, professionalism is the main driving force for ethical conduct. There may not be a common global standard on the code of ethics of pharmacists but every nation will have a set of guidelines on the code of ethics or code of conduct for pharmacists. Each country's pharmacy professional body, board or council will use the code of ethics or code of conduct to safeguard the profession. Such a code of ethics or code of conduct will be used as a guide by the professional body on action to be taken for misconduct or infamous conduct of the member pharmacists.

It is globally known that the national Board of Registration of Pharmacists or similar bodies provides a code of professional conduct to ensure the highest degree of ethical and moral practice by pharmacists. These bodies will also monitor pharmacists to ensure they meet the standard of ethics as stipulated. The pharmacist code of ethics is to ensure that consumers

are receiving the highest quality drug products with assured safety and efficacy. Furthermore the national Board of Registration of Pharmacists or similar bodies will also usually set standards for the curriculum of pharmacy in their country. There will be a check list on the content of the curriculum, where will include a requirement on the teaching of ethics as a formal course.

2. Pharmacy historical role

Briefly we can learn about the historical role of a pharmacist or a pharmacy by going back into history, from the era of the Greeks and the Romans, the influence of the Muslim Caliphate, the era of the crusaders and the era of the industrial revolution in Europe and the establishment of a new nation, the United States of America.

The art of pharmacy was first practiced in Ancient Babylon around 2600 BC. In this era the priest, physician and pharmacist was the same person. The Arabs were the first to separate the art of pharmacy from physician and in the eight century they establish the first private pharmacy in Baghdad. When the European countries were exposed to Arabian influence, public pharmacies began to appear. However, it was not until about 1240 A.D. that pharmacy was separated from medicine.

3. Current global role of pharmacist

The role of the pharmacist is changing drastically with the traditional activities of the pharmacist such as extemporaneous compounding of medicines reducing and pharmacist becoming more like a walking encyclopedia for drugs, fulfilling the doctor's needs by giving advice and information on use of drugs, providing correct dosage forms, assuring the efficacy and quality of the dispensed or supplied medicinal products, formulating dosage forms and manufacturing drugs.

There has been a great transition in the profession and patient care has become the pillar of the practices. Now the pharmacy profession is not only related to dispensing and distribution of drugs or sometimes being regarded as a "glorified store keeper". A lot of societal and political influences and the development of new legislative instruments in most nations have paved the changes in the pharmacy profession that we are seeing today. Pharmacists now have a bigger role as global players and in the adoption of global standards so as not to be left out or left behind in the global race. This also has to be in line with global trends and forecasts for the pharmaceutical industry.

4. The basis of ethics for the pharmacy profession

Generally, the pharmacist is responsible for dispensing and compounding drugs or preparing suitable dosage forms for administration of drugs where overall these include patient pharmaceutical care in the clinical area, manufacturing, community pharmacy and research, with the latter including collection, identification, purification, isolation, synthesis, clinical trials, standardization and quality control of medicinal substances. All the above responsibilities of a pharmacist formed the basis for the requirement of a set of ethics guidance.

5. Pharmacy legislation

Pharmacy legislation generally includes the regulations for the practice of pharmacy, the sale of medicines and poisons, the dispensing of narcotics and other drugs of abuse, sale of drugs, quality assurance on drug manufacturing and advertising of drugs and medical devices. A pharmacist should dispense drugs within the provisions of the legislation of the country in which he practices. Such legislation recognizes the national pharmacopoeia along with international pharmacopoeia such as the United States Pharmacopoeia (USP), European Pharmacopoeia (EP) and British Pharmacopoeia (BP). These pharmacopoeias define products used in the practice, the purity of the drug, dosages and strength, and ensuring the standard for drugs in term of quality, safety and efficacy. The World Health Organization (WHO) traditionally plays a very important role to ensure that drugs in the global market are safe and affordable by poorer nation and, along with that, encouraging developed nations to harmonize their standards requirement to facilitate drug accessibility.

6. Pharmacist in different clusters with different ethical issues

The areas of pharmaceuticals can be clustered according to practices and their ethical issues.

6.1 Ethical issues in clinical pharmacy practice

Ethical issues arise as part of daily practice in the clinical setup in hospitals.

6.1.1 Patients pharmaceutical care

Pharmaceutical care is the current practice in pharmacy where pharmacists are responsible in view of drug therapy for the purpose of achieving best outcomes that promote a patient's quality of life. Clearly there are ethical issues in this new development. Among others, the ethical issues in pharmaceutical care practice are patient confidentiality and privacy, patient autonomy, duty to warn, competencies in deciding the best medication to be procured.

On the confidentiality and privacy issues, there is a general duty recognised by professional ethical codes which apply to all health and social care staff and this also includes pharmacists and their staff. Respecting confidences between pharmacists and patients enables patients to disclose the sensitive information that pharmacists need to provide pharmaceutical care (Wingfield et al., 2004). Without an assurance that confidentiality will be maintained, patients may be less willing to disclose information, resulting in obstacles to effective pharmaceutical care.

The autonomy of a pharmacist is always influenced by the unavoidable physician-patient relationship. This autonomy interfaces with the ethics of a physician. Pharmacists are always in a conflict position weighing the patient's rights for information and the physician's ethics for non-disclosure. A good example will be the non-disclosure of the side effects of a drug by a physician, e.g. in the case of prescribing a cancer drug a physician may not want a patient to be informed of the side effects as this may lead to patient in compliance.

The above topic on autonomy is also closely related to the duty of the pharmacist to warn on pharmaceutical issues and products. Warning a patient has to be balanced with the doctor's instructions and a conflicting situation need to be avoided. It would be unethical for a

pharmacist to directly advise against a doctor's instruction to a patient without first informing the doctor involved.

The pharmacist, as a health professional in systems where value for money is an issue, requires competencies in deciding the best medication. The pharmacist is involved with making decisions on which drugs to include on a national formulary and to set guidelines on which drugs are used in a national hospital setting. Pharmacists have an active role in this decision-making process so currently most pharmacy teaching institutions have a module termed pharmacoeconomics in their curriculum, in which students will be trained to consider all issues in deciding which is the most economical drug based on the current literature. Consideration will be given to quality of life. The aspects covered include minimization of drug costs, cost effectiveness of drugs, cost utility, cost benefit, overall cost of illness, cost consequences. These aspects form the economic analytic technique that provides valuable information to pharmacists in making suggestions on which drugs will be more economical overall. The International Society for Pharmacoeconomics and Outcomes (ISPOR) gives the following definition: "Pharmacoeconomics is the scientific discipline that evaluates the clinical, economic and humanistic aspects of pharmaceutical products, services, and programs, as well as other health care interventions to provide health care decision makers, providers and patients with valuable information for optimal outcomes and the allocation of health care resources. Pharmacoeconomics incorporates health economics, clinical evaluations, risk analysis, technology assessment, and health-related quality of life, epidemiology, decision sciences and health services research in the examination of drugs, medical devices, diagnostics, biotechnology, surgery, disease-prevention services." (ISPOR 2011).

Members of the decision-making team should not have personal vested interests in companies which manufacture drugs, e.g., owning stocks, research support, speaker's bureau.

6.1.2 Interaction with other medical professionals

Pharmacist in clinical practice have to work with nurses, doctors and other medical professionals and they are very much needed to give advice on the latest medications, drug substitution, drug costing and everything to do with drugs or related devices. Often, pharmacists do not work directly with the patient, but rather with other health care professionals to complement the patient's therapy. However, there are opportunities for pharmacists to see patients when accompanying physicians and nurses on ward rounds. This will be one of the ethical issues where pharmacist is there to assist the other professionals but not to comment on short comings involving other professionals on the therapy. Sometimes it is difficult to balance the two and pharmacists have to be professional in handling such matters. A substantial percentage of a pharmacist's daily work will be interacting with other health professionals and this has to be done in an ethical manner.

6.2 Ethical issues in community pharmacy practice

Community pharmacy traditionally had a drug product focus wherein the primary business emphasis has been on drug distribution. In recent years, this emphasis has evolved,

resulting in pharmacy becoming a more patient centered profession which emphasizes a shared responsibility between the patient and pharmacist for optimal drug therapy outcomes. This section explores the ethical issues involved in modern community pharmacy practice and discusses the related ethical dilemmas.

6.2.1 Dispensing of drugs

Ethical dispensing of drugs, medicinal devices and other products presents part of the requirement for rational drug therapy. Dispensing is not merely giving away drugs just like a vending machine based on prescription issued by doctors. Pharmacists need to dispense a drug professionally where this practice will include giving information of drugs in use or new drugs, information on side effects, drug interactions with other drugs or with food, recommendations on drug administration for unique situations (e.g. renal failure), information regarding appropriate drug dosage based on various factors (e.g. renal clearance, weight), information on national drug registration, information on administration of drugs, warnings, precautions and contraindications, storage conditions and stability of drugs.

Pharmacists can implement their right to refuse to dispense based on professional judgment. It is specified in the many national pharmacy laws that a pharmacist can refuse to dispense, if in the pharmacist's professional judgment, the prescription does not seem to be valid, or if filling the prescription as written could cause inadvertent harm to the patient. The basis of a "pharmacist's professional judgment" will be based on the pharmacists' knowledge of the safety of the drug where ethically pharmacist should not allow hazard to the patient's health and welfare or anything which might result in suffering.

The question is whether a pharmacist has the right to refuse to dispense based on personal beliefs. An example could be whether a Muslim pharmacist can refuse to dispense products derived from pork. This issue can only be investigated by reading in-depth the relevant religious beliefs because, as a human being, a pharmacist also has freedom of speech. This may not be a good example as pork material can be used by Muslims in emergency cases if there is no substitute. Another question that arises will be whether it is ethical to dispense a substitute based on religious beliefs.

On the issues of online dispensing there are a lot of controversies and legal issues. According to Constance HF, Hawkin EW and Steven M in Mayo Clinic Prod. 2004 all these issue fall into 3 major categories: independent internet-only sites, online branches of pharmacies and sites representing partnerships among neighbourhood pharmacies. They further elaborate that potential benefits of online pharmacies include increased access, lower transaction and product costs and greater anonymity. However, they also stressed that online pharmacies have generated controversies, including the use of "cyberdoctors" on some sites, the dispensing of drugs without prescriptions from other sites and the import of prescription medications. Although some online pharmacies are legitimate and likely provide benefits to patients, other online pharmacies engage in questionable practices. Several nations have tried to regulate internet pharmacies as there are potential risks along with benefits of using online pharmacies. All these issues go back to the ethics of the pharmacist involved in such dispensing.

6.2.2 Prescribing of Pharmacy Only Medicines (POM)

Based on the classification of certain drugs by certain nations, pharmacist can dispense without a doctor's prescription or indirectly the public can buy preparations directly over the counter from pharmacist. This involves ethical practice by pharmacist where such sales should be in line with the authority guidelines to ensure public safety. Dispensing has always been the pharmacist's right but in some nations where the number of pharmacist is small the idea of the pharmacist's dispensing right is not implemented. In such countries the doctor does the prescribing and the dispensing together. Pharmacists in these countries are given the right to dispense without prescription certain categories of drugs to the public. In such conditions the ethics of the pharmacist is very much needed so that medicines that are being sold do not harm the public. For example in some countries certain drug like oral contraceptives (OCs) are being sold without prescription by pharmacists. In such cases the pharmacist has to input a high level of ethical control so that OCs are not simply sold to youngster and this matter needs judgment from the pharmacist to ensure safety to the public and to avoid certain drugs being abused. Another issue is the abusive use of local steroids in dermatological preparations, as these preparations are regulated as POM by some nations and they are readily available through pharmacies, and the pharmacist has to apply their knowledge to advise the public on the use of such preparations.

Pharmacists have a professional obligation as the gatekeepers of non-prescription medicines. The public may be able to obtain readily-accessible efficacious medicines through a pharmacist but the sale has to be immediately supervised and given proper information and consultation by the pharmacist. In most nations this direct dispensing by a pharmacist will carry legislative responsibilities to the pharmacist for ensuring proper sales and recording. Some countries use the term "immediate supervision" in their regulation on pharmacist dispensing without prescription. This means that pharmacist has to be available in the premise where the dispensing was done.

This category of drugs (non-prescription drugs) is one of criteria which drive toward self medication. With this classification of drugs, the public can buy preparations that were previously available only on prescription. A study in the UK shows that sales of over the counter medicines are now equivalent to a third of the NHS drugs bill (B. Colin and B. Alison 1996). This study also showed that over any two week period, nine out of 10 adults in the UK will experience at least one ailment, where non-prescription medicines are used to treat one in four of these episodes. There is a move toward smart self-medication and some governments throughout the world see self medication as a way of shifting some of the cost of healthcare onto consumers.

6.2.3 Patients' drug consultations

Pharmacists are professionals, expected to be very knowledgeable on drugs and to give drug consultations to the public in an ethical manner. Drug consultation is needed to advise patients on drug selection, drug dosage, understanding drug effects and side effects and interaction of drugs with other drugs or with food. This consultation can also include advice on general health information, management of certain conditions, diet and exercise. Some nations regulate the layout of a community pharmacy to allocate an area for patient counseling and drug information. It is globally accepted that drug consultations are free.

Public may request consultation with a pharmacist during their visit to a community pharmacy. Pharmacist cannot assume that they know the patient's best interest, the patient need to provide information and assist the pharmacist in their decision making (Latif, 2001).

Conventionally a pharmacist needs to keep records on all drug transaction as required by national laws. These records are among others for a pharmacist to monitor the dispensing of drugs to provide accountability when it comes to drug recall. These records will also capture the trends of drug usage and of prescribing by physicians. Community pharmacists also need to maintain individual records for patients who frequently consult them for advice on their medication. In such cases pharmacists have to ensure that personal medical records are kept private and confidential. All such records should be handled personally by the pharmacist and the national Code of Conduct of Pharmacist needs to address this matter to ensure pharmacists respect such confidentiality. Any breach of the confidentiality requirements is a great breach of ethical conduct. If in the case where records are kept electronically using a computer, the pharmacist has to ensure and validate the security of the records. This can be done by adoption of certain software which uses a password for access and amendments to records will be recorded in the history so that the old record can easily be retraced.

6.2.4 Extemporaneous pharmaceutical preparations

Extemporaneous preparations are products, which are dispensed immediately after preparation and not kept in stock (Pharmaceutical Inspection Convention, 2008). Extemporaneous preparations can be considered as unlicensed drugs where this preparation does not by law need to be concerned with quality, stability, bioavailability, efficacy and safety. As there are no published standards in the compendium, the standard depends very much on the professionalism of the pharmacist preparing the preparation. The pharmacist is referred to as the person who is skilled in the art. The uniformity of content, selection of safe excipients and stability issues form the challenges in the preparation of extemporaneous products. Dispensing of extemporaneous preparations of various dosage forms needs to have some ethical guidance, where this will involve the following issues:

6.2.4.1 Assuring quality in extemporaneous preparations

Extemporaneous preparations are preparation of dosage forms for particular patient consumption. There is no requirement of submission for registration with the authority so the quality of this type of preparation relies solely on the pharmacist and ethical issues on this matter need to be considered. Efforts to improve the quality of licensed and manufactured medicines are always on the agenda of pharmaceutical authorities but extemporaneously prepared products are still needed. So the pharmacist has the responsibility of ensuring that accurate and effective doses and dosage forms are made to achieve optimal drug therapy for certain groups like children and the elderly. Extemporaneous preparation is one facet of unlicensed drug use which can be a modification to commercially manufactured products such as the preparation of suspensions or powders from tablets or a preparation from individual raw materials where the pharmacist needs to be guided with some information from a reliable compendium. Extemporaneous preparation is popular in paediatric cases as this is to overcome the problems associated with the lack of approved medicines for children (Giam and McLachan, 2008).

Among the compendiums concerned with extemporaneous to which the pharmacist ethically has to refer are: the European Pharmacopoeia (2007), which is used as an official regulation for extemporaneous preparations, the British Pharmacopoeia (BP), the United States Pharmacopeia (USP), the Australian Pharmacopoeia Formulae (APF) and Martindale (Glass and Haywood, 2006). General instructions of the extemporaneous preparation are presented in Medicinal Products for Human and Veterinary Use: Good Manufacturing Practice (Eudralex, 2007) and in PIC/S Guide to good practices for the preparation of medicinal products in healthcare establishments (Pharmaceutical Inspection Convention, 2008).

6.2.4.2 Stability issues of extemporaneous preparations

Issues affecting the stability of extemporaneous preparations may include degradation of the drug, evaporation of the vehicle, loss of uniformity, change of appearance, change of bioavailability and toxicity caused by degradation products. There should be some form of stability evidence for extemporaneous preparations.

The stability of extemporaneous preparations refers to the chemical and physical characteristics of the preparation and the microbiological conditions (US Pharmacopeia, 2008). The shelf life of an extemporaneous preparation is predicted after an accelerated stability study has been carried out but more often extemporaneous preparations are given arbitrary shelf-lives (Costello et al., 2007). It is pertinent for a pharmacist to ensure that an extemporaneous formulation will remain within its physical, chemical and microbiological set conditions during storage for a specified time (Florence and Attwood, 2006). A short expiry period may be inconvenient for patients but a long expiry date will put the product and the user in jeopardy.

It is clear that it is the responsibility of the pharmacist to at least perform a stability study and predict the shelf life of a commonly prepared extemporaneous preparation so that there is evidence to support the quality of the extemporaneous preparation.

6.3 Ethical Issues in manufacturing of pharmaceutical products

Pharmaceutical manufacturers not only manufacture drugs and dosage forms but they also develop, produce, and markets drug licensed for use as medications. Manufacturers are subjected to a variety of laws and regulations regarding the manufacturing, testing and ensuring quality, safety and efficacy and marketing of drugs.

6.3.1 Quality assurance in pharmaceutical manufacturing

As defined by most documents, quality assurance is a system of actions devoted to ensure, with reasonable confidence, the quality of a product for its intended purpose. Ethics are pertinent to quality assurance as the person involved strives by taking actions to meet quality level goals, which contributes to quality assurance.

Generally we can make the assumption that the quality assurance concept covers all matters that individually or collectively influence the quality of a product. Generally, the keynotes of quality assurance are: quality systems are the foundation for effective management of an organization; quality systems are based on the philosophy of prevention; quality systems

address the whole business process; quality systems consist of structured documentation to provide control; quality systems ensure a complete record of what you have done and complete documentation of what to do. With these keynotes, clearly quality assurance needs high ethical conduct from a pharmacist in order to truly build quality into pharmaceutical products.

Pharmaceuticals quality assurance can be divided into four major areas: quality control, production, distribution and inspections. To support quality assurance, there are standards and guidelines developed to supervise the procedures toward achieving quality. Quality assurance will have guidance documents for production, testing and distribution of pharmaceuticals. Among the documents are: guidelines for good manufacturing practices; guidelines for regulatory approval of pharmaceuticals; prequalification of pharmaceuticals, laboratories and supply agencies; and guidelines on quality control testing. Different countries will have their own set of guidelines which will be in line with their own national pharmaceutical legislations. For international purposes (usually for export of pharmaceutical products) international guidelines prepared by the World Health Organization (WHO) or the International Conference on Harmonisation (ICH) will be adopted.

6.3.2 Good manufacturing practice

Good Manufacturing Practice (GMP) is part of a quality system covering the manufacture and testing of pharmaceutical dosage forms or drugs. It outlines the aspects of production and testing that can impact the quality to a product. GMP ensures that quality is built into the product from the first step of production, not merely testing for quality at the end of the production line. GMP is concerned with both production and quality control (QC), where QC is a set of actions to test the acceptability of the raw materials, processed materials, final product and packaging material.

The basic requirements of GMP include: ensuring that all manufacturing process are clearly defined, systematically review for consistency in the production of a medicinal product of the required quality and specification and ensuring that critical steps of the manufacturing process and significant changes to the process are validated.

To ensure GMP achievement, the responsible person such as a pharmacist needs to ensure that the organization has adequate and appropriately qualified and trained personnel, adequate premises and space for the manufacturing, suitable equipment for the intended purpose with a proper plan for preventive maintenance, correct materials, containers and labels being used to maintain the quality of the product, approved procedures and instructions for manufacturing and suitable storage and transport.

A pharmacist in the GMP organization should also make sure that a system is available to recall any batch of the product, from sale or supply if a defect has been identified in a batch. Pharmacists also need to ensure that complaints about marketed products are examined, the causes of quality defects investigated and appropriate measures taken in respect of the defective products and to prevent reoccurrence of the defect. Pharmacists need to implement corrective and preventive measures to assure defects are corrected and do not happen again in future.

Clearly a pharmacist is key personnel in view of GMP. This key personnel status needs a profession and a person with high integrity. So, as a pharmacist is a professional, governed by a professional body, they should practice within the code of ethics in GMP facilities.

6.3.3 Good storage practice and good distribution practice

The quality of pharmaceutical products can be affected by a lack of adequate control over numerous activities which occur during the storage and distribution process. Good Storage Practice (GSP) is also part of a quality system covering the storage of pharmaceutical dosage forms or drugs. It outlines the aspects of storage that can impact the quality of a product after it has been manufactured in GMP manner. Good Distribution Practice (GDP) is also part of the quality system which covers the distribution of pharmaceuticals. The storage and distribution process should also be emphasized with regard to the need for establishment, development, maintenance and control over the activities involved. The guidelines for storage and distribution will assist in ensuring the quality and integrity of pharmaceutical products in all aspects of distribution and storage. In order to maintain quality, safety and efficacy, every activity in the storage and distribution of pharmaceutical products should be carried out according to the principles of GMP, GSP and GDP.

The storage and distribution of pharmaceutical products are different in different countries. There may also be differences between systems used in the public and the private sectors. All persons involved in any aspect of the storage and distribution of pharmaceutical products are ethically responsible, starting from the premises of manufacture to the point of supply to health establishments, such as private pharmacies, hospitals and clinics for supply to the patient. So all parties involved in trade and distribution, pharmaceutical manufacturers, including manufacturers of finished products, brokers, suppliers, distributors, wholesalers, traders, transport companies and forwarding agents, need to abide by the national requirements on storage and distribution.

One important issue in GSP and GDP is the cold chain system in handling and storage of certain categories of pharmaceuticals that require refrigeration, e.g. certain vaccines. A cold chain is a concept of supply chain which emphasized on temperature-controlled which is to ensure that the low temperature chain is unbroken according to series of storage and distribution activities by maintaining a given temperature range. For pharmaceuticals, it is used to ensure the shelf life of products such as vaccines or other products which is temperature sensitive. Cold chain is important in the supply of vaccines to clinics in hot climates. Disruption of a cold chain may develop consequences of non-effectiveness vaccination. Cold chain is part of the good manufacturing practice (GMP) which all pharmaceuticals and biological products are required to follow. Cold chain must be validated to ensure that there is no negative impact to the safety, efficacy or quality of the pharmaceuticals. GMP requires that all processes that might impact the safety, efficacy or quality of the drug substance must be validated, including storage and distribution of the drug substance. A cold chain should be managed ethically by validation of a distribution process, which among the needs of cold chain are logistics of shippers (providing tracking of the status of the temperature maintenance with prove of documentation), using refrigerator trucks, refrigerated warehouses, products are insulated with specialized packaging, temperature data loggers and tags to help monitor the temperature history of the products while shipping or kept in warehouse or while they are kept by the pharmacist or physician,

every step of the cold chain needs to be properly recorded. From this brief explanation on cold chain we can see clearly that those who manage pharmaceutical which requires cold chain need to be very ethical to ensure the efficacy and safety of the product. There can be serious breach of ethics if a product is being reinstalled with a new tag when its original tag has shown that the cold chain had been broken.

6.3.4 Ethics of pharmacists in handling product complaints and product recalls

Most nations regulate that all complaints and other information concerning defective pharmaceutical products, must be carefully investigated according to written procedures. The pharmacist in charge of complaints is responsible for initiating the investigation immediately. The investigation shall be documented in writing. If a product defect is discovered or suspected in a batch, the pharmacist should also take into consideration to determine whether other batches are also affected. If the defect is life threatening, the pharmacist should take immediate action by all reasonable means, whether in or out of business hours to recall the product.

Pharmacists should always be prepared for product safety alerts, where products can be in a situation of not conforming to the safety specifications. When there is a risk of significant hazard to consumers from a product which has been distributed in the market, pharmacists should take the responsibility of disseminating the safety alert through mass communication media available, including newspapers, radio and television. Fast action should be taken according to documented procedures to remove the defective product from sale or use. Clearly the pharmacist is responsible to establish a system to recall products known or suspected to be defective from the market promptly and effectively. The pharmacist should be ethical, when deciding the fate of the recalled products. The recalled product may be reworked if it meets appropriate standards and specifications. The recalled product should be destroyed if the condition of the product casts doubt on its safety, identity and quality. The pharmacist has to be ethical in making all these decision where priority should be given to the safety of human beings and not to monetary considerations.

6.4 Ethical issues on wholesale, supply, import and export of drugs

Wholesale, supply, import and export are all actions on distribution of drug which are controlled by permits and licenses. Pharmacists trusted with such permits or licenses need to show a high level of ethics as drugs can be diverted to illicit channels for misuse and drugs can also be counterfeited and patient safety is always at stake. The ethical need in this issue is paramount for categories of drugs which have tendencies to be abused. Dangerous drugs such as morphine, fentanyl or pethidine or psychotropic substances such as diazepam or barbiturates and their derivatives need to be dealt with a high level of ethics as pharmacists are trusted as guardians to these highly abusive drugs and the tendency of being abused by pharmacists is high as the sales can be very lucrative to the pharmacist.

Globally most nations are member of the International Narcotic Control Board (INCB), United Nations (Vienna). As stipulated by the INCB, import and export of dangerous drugs or psychotropic substances need to be authorized by the importing nation and also the exporting nation following the procedures set by the INCB. An import authorization will be issued to the pharmacist by the competent authority of the importing country. Upon

receiving a copy of the import authorization from the competent authority of the importing country, the competent authority of the exporting country will issue an export authorization to allow the exporter to export the product. It will be unethical for a pharmacist not to follow the requirement of the INCB in terms of import and export of such drugs.

6.5 Ethical issues in research and clinical trials

Good Research Practice (GRP) should ensure that research is well-planned, appropriately designed and ethically approved. The requirement of ethics committee approval is a stringent requirement for medical related research where there may be use of animal or human subjects. Approval is needed from the institutional review board (IRB) or institutional ethics committee (IEC) of the respective establishment on research involving humans or human tissues, medical records or surveys of certain research issues. In the US, an IRB is a board, a committee, or a group of people formally designated by an institution like hospitals, academic medical centers, government units, and others engaged in conducted or supported health research activities involving human subjects, to review research involving humans as subjects. An IRB has the authority to approve, modify, or disapprove related research activities. Upon approval, IRBs must conduct periodic reviews of such research. In the US, all IRB must have not less than five members with varying backgrounds and each member must be sufficiently qualified through the experience and area of expertise. The membership should also be as diverse as possible in term of race, gender, and cultural backgrounds. IRB should not include member who has conflict interest, except on special cases where needed. All IRBs must include at least one member who are in scientific areas and at least one member who are in nonscientific areas. Some nation do not have IRB but instate they have institutional ethics committee (IEC) with similar set up of members and function as an IRB.

Drug development research is one of the main activities of a pharmaceutical company involved in research. Modern drug development follows the following key stages: program selection (choosing the disease target), identification and validation of the drug target, assay development, identification of a lead compound, optimization of the lead compound, identification of a drug candidate, preclinical study (a broad study encompassing animal studies, toxicity studies and pre-formulation studies), clinical trials on human subjects, registration and release of the drug to the market and follow-up monitoring (adverse drug reaction reporting). Generally, pharmaceutical companies will invest more on research for drugs which are likely to be more lucrative in their sales. Usually those diseases suffered by people in developed nations will be more attractive for the pharmaceutical companies. For example, not much research is being carried out by pharmaceutical companies on drugs for AIDS as the vast majority of AIDS sufferers are from the third world such as those from the African continent. Ethically this is not right but the pharmaceutical companies need to pay back the money which has been spent on research.

6.5.1 Preclinical research

Preclinical research involves studies of a drug before it is approved for studies on humans. These studies are designed to collect data at the earliest stage (such as cell culture study) to confirm activity. Among the studies can be spectroscopic studies to identify the chemical structure of the drug-like compound and animal studies using wide-ranging doses of the

study compound to obtain preliminary effectiveness and toxicity data along with determination of the pharmacokinetics of the new compound in animal models and to predict the pharmacokinetics in humans. Preclinical studies will assist pharmaceutical companies to decide whether a drug candidate has scientific merit for further development.

Preclinical studies must adhere to Good Laboratory Practice (GLP). The International Conference on Harmonisation (ICH) guidelines for GLP should be adopted by nations as a standard. An ethical issue here is for the pharmacist involved in the study to abide by the guidelines stipulated. Furthermore the use of animals in the studies needs to have clearance from the animal ethics committee. Animals are used to study the toxicity, including studies on organs that are targeted by the new compound, as well as studies on any long-term carcinogenic effects or any adverse effects on the reproduction system. Some nations have even made it compulsory to study the effects on genes. Information collected from preclinical studies is important so as to ensure the follow-up clinical trials on humans is safe and there are no unexpected adverse effects. Although animal studies in pharmaceutical research have been reduced in recent years both for ethical and cost reasons, most research will still involve animal-based testing for the need of similarity in anatomy and physiology that is required for diverse product development.

Another important component in preclinical studies where pharmacists play a very important role are the pre-formulation studies. Pre-formulation is a branch of pharmaceutical sciences that utilizes biopharmaceutical principles in the determination of physicochemical properties of a drug substance. Commonly evaluated parameters of the new compound in pre-formulation studies are solubility, ionization constant (pKa), partition coefficient (Log P), dissolution behaviour, stability, solid state properties such as crystal forms/polymorphs, water sorption behavior, surface properties, particle size and shape, and other mechanical properties. In depth pre-formulation studies are needed as this will determine the end dosage form of the new drug. Data from these studies will be used to decide whether the dosage form will be an oral solid dosage form or an intravenous dosage form or any other best route of administration. At this stage the dosage form determination is pertinent as the new compound will be given to humans for the purpose of clinical trials.

6.5.2 Clinical trials for new drugs

In the study of a new chemical entity for the purpose of developing a medicine, clinical trials in humans are among the last steps to be carried out. They will only be started after the chemical entity has gone through extensive preclinical studies and found to be fit and proper for human use and a dosage form for humans has been developed. Clinical trials enable us to evaluate and assess the effectiveness of a new medicine in the treatment of a particular condition and also help to disclose possible side effects. Before such a new medicine can be approved by the regulatory authorities, it must be proven to be efficacious and safe in the targeted patient population.

Clinical trials will involve human subjects as volunteers so it is of paramount importance to ensure the safety and well-being of these volunteers and that all trials are conducted in accordance with global ethical principles. Clinical trials deal with human beings so the human rights and dignity of people participating in clinical trials need to be protected. Clinical trials follow a set of global accepted protocol in line with the requirements of the

national health authority. All clinical trials need to be approved by the national institutional ethics committee (IEC) in the country where they are carried out. These global standards are not to be compromised. Clinical trials must be conducted in the same way all the time, no matter where in the world and by whom they are carried out.

Investigators must carefully select the subjects to participate to have the right profiles, obtain informed consent from each subject and take steps to ensure the well-being of the subjects throughout and after the trial. Clinical trials must undergo independent scientific and ethical review and approval and are subject to audit by the national authorities during or after the trial. All clinical trial results must be made publicly available.

Clinical trials on humans are usually carried in a randomised and blinded manner, so that subjects, and in some trials also the investigators, do not know if the treatment that the subjects are receiving is the new drug or the control treatment. These trials may use placebo as a control. This means that test subjects are randomised to receive either the new medicine or a placebo. This technique is termed as “randomized double-blind, placebo-controlled trial” where a group of the subjects are given the treatment, another group are given placebo, and neither the researchers nor the subjects know which is which until the study ends. For over the years researchers have established that for most types of trials, only a randomized double-blind, placebo-controlled study can answer the question whether a drug in a trial really work. Commonly ethics committees have reservations on the use of a placebo as it 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.

Generally clinical trials are clustered into four different phases (Spilker, Bert., 1984). Phase I involves the first testing of a new compound in human subjects for the purpose of establishing the tolerance of healthy human subjects at different doses, defining its pharmacologic effects at anticipated therapeutic levels and studying its absorption, distribution, metabolism, and excretion patterns in humans. Phase I can involved 100-200 subjects. Generally Phase 1 studies will assess the most common acute adverse effects and examine the doses that patients can take safely without serious side effects. At this stage we begin to clarify what happens to the new drug when it is in the human body. Question like how is it metabolized, how much of it (or a metabolite) gets into the blood and various organs, how long it stays in the body, and how the body gets rid of the drug and its effects, will hopefully be answered.

In Phase II, controlled clinical trials with the new medicine give information on its potential usefulness and short term risks. A relatively small number of patients, usually no more than several hundred subjects, are enrolled in phase II studies. At this stage the efficacy of the medicine is fully established and the dose response relationship is established. This phase usually includes an active comparator (as control).

Phase III involves general studies of the new medicine safety and effectiveness in both hospital and outpatient settings. This phase gathers information on the medicine’s effectiveness for the specific indications, determines whether the medicine causes a broader range of adverse effects than those exhibited in the phase I and II studies and identifies the best way of administering and using the drug for the purpose intended. If the drug is

approved for registration, this information forms the basis for deciding the content of the product label. Phase III studies can involve several hundred to several thousand subjects.

Phase IV generally takes place after the medicine has been approved for marketing. It comprises market surveillance studies as required by authorities globally. As this phase takes place after market authorisation is given, it determines the effectiveness and safety of the product in an even wider variety of populations. It may also be conducted on request from authorities as a condition for market authorisation approval to address specific safety issues. The extensiveness of the clinical trial has to be implemented together with the global requirement of other human right declarations.

Clinical trials should always be conducted according to global human rights declarations such as the Declaration of Helsinki, the Nuremberg code, the Belmont report and the International Conference on Harmonisation (ICH) guidelines for Good Clinical Practice. The interest and well-being of the trial subjects should always prevail over the interest of science, society and commerce. Clinical trials will only be conducted if they can be scientifically and medically justified and potential benefits outweigh potential risks. Children should only be included in a trial if there is no other research alternative.

Subjects participating in a clinical trial should, after the study has finished, be offered the best possible treatment, at the discretion of the investigator. Everyone has to ensure transparency of clinical trials and clinical trial results for the good of humanity.

It is interesting to know the historical development of ethics consideration in using human subjects for clinical trials. In the early twentieth century there were no regulations regarding the ethical use of human subjects in research and no requirements for ethics approval or an institutional review board (IRB) whatsoever. An eye opener to the need of ethics consideration for use of human subjects is the well known Nuremberg tragedy where during the world war, German physicians conducted medical experiments on thousands of concentration camp prisoners without their consent and most of the subjects of these experiments died. A military tribunal for war crimes and crimes against humanity was set up and as a result of the trial the Nuremberg Code was established in 1948. The Nuremberg Code states that subjects should give consent and that the benefits of research must outweigh the risks.

Realizing the need of ethical implementation on the use of human subjects the World Medical Association established the Declaration of Helsinki in 1964, guiding medical doctors involved in research using human subjects. The declaration stated that all research with humans should be based on the results from laboratory and animal experimentation, research protocols should be reviewed by an independent committee prior to initiation, informed consent from research participants is compulsory, research should be conducted by qualified individuals and the risks of research should not exceed the benefits.

It is ironical that the Declaration of Helsinki did not stop the unethical use of human subjects in the case of Tuskegee Syphilis Study conducted by the U.S. Public Health Service between from 1932 to 1972. Six hundred low-income African-American males, 400 of whom were infected with syphilis, were monitored for 40 years. Free medical examinations were given; however, subjects were not told about their disease. Even though a proven cure (penicillin) became available in the 1950s, the study continued until 1972 with participants being denied treatment. Many subjects died of syphilis during the study. The study was

stopped in 1973 by the U.S. Department of Health, Education, and Welfare only after its existence was publicized and it became a political embarrassment.

In response to this, the United States created a Commission for the Protection of Human Subjects, which drafted the Belmont Report in 1979, a foundational document for the ethics of research with human subjects in the U. S. The Belmont Report stated the basic ethical principles that should assist in resolving the ethical problems that surround the conduct of such research: respect for persons, beneficence and justice. These three basic principles were used to enforce the need for informed consent, the need to assess the risks and benefits and the need for proper selection of subjects.

Clearly the Helsinki Declaration, Nuremberg Code and the Belmont Code are pertinent to the pharmacy profession as pharmaceutical companies are parties who initiate clinical trials for their new drugs or new formulations. Pharmaceutical companies will engage Clinical Trial Organization (CRO) to manage the clinical trial. The CRO will ensure that the doctors involved abide by all the requirements of Good Clinical Practice which encompasses the criteria stipulated in the declarations and codes.

7. Ethical marketing of pharmaceutical products

Pharmaceutical organizations are made up of pharmacists who are governed by their professional bodies, so each pharmacist has a duty to uphold an ethical relationship within the business. They are required by their code of conduct to care for the health and safety of human beings. A question frequently raised is how pharmacists can ensure that ethical standards are upheld when pharmaceutical companies have large investments and stakeholders to protect. Because of this several nations not only regulate pharmacists as people that should abide by the code of ethics but also pharmaceutical companies.

It is very misleading to believe that ethical equates to lawful and it may be untrue to think that by being lawful an organization, activity or person is ethical. Look around us, many unethical practices are entirely lawful. For example mercurial soap used for skin whitening is unlawful to be marketed in all developed nations but some of these nations allow the manufacture of such products for export markets. Some nations allow manufacturing of patented product but still the act of producing patented products is unethical.

Pharmaceutical companies use the service of sales representatives in marketing their products. These sales representatives need to be adequately trained and possess sufficient medical and technical knowledge to present information about the products in an accurate and responsible manner. The sales representative should not only be able to provide accurate information, but should also not to exaggerate the capabilities of the product. He or she should be able to talk about the property of the product or the mode of action of the drug and possible side effects. It is a well known practice for a sales representative to give free samples to physicians. All these free sample need to be accounted for by way of recording by the pharmaceutical company so that the traceability of the product can be maintained for the purpose of product recall. The practice of giving other gifts by pharmaceutical companies to physicians is unethical. A good example is giving free overseas trips under the pretence of sponsorship for attending conferences or workshops. In this case the pharmaceutical companies and the physician can both be guilty of misconduct under their own code of conduct.

Pharmaceutical organizations must not only see how much profit can be made but also how ethical is the profit that is made. Pharmaceutical organizations in many countries have developed a code of pharmaceutical marketing practices to be adopted by their members. Among the recommendations is that all marketing activities under the code must conform to existing and relevant government legislation governing the practice of the pharmaceutical industry. The code stresses that members should have good management of complaints which documented procedures of investigation and with set time frames for processing each complaint lodged. Corrective and preventive outcomes of complaint investigation should also be documented. Generally the code also outlines all possible issues in disseminating accurate, fair and objective information to the medical and allied professions so that rational prescribing decisions can be made. Members are required to follow high standards of conduct and professionalism in the marketing of pharmaceutical products. Such a code should also have ethics committee to hear, receive and deliberate on all breach of ethics issue. This committee should set penalties for breach of the code and publish the names of companies, which have been found to be in breach of the code, which may result in them suffering adverse publicity.

8. Pharmacists role in complementary & alternative medicines

Complementary and alternative medicines are health practices that have the component of pharmaceutical preparations, dietary supplements, and traditional forms of health practice such as acupuncture, Chinese medicine, homeopathy, etc. Very recently complementary and alternative medicines have become an important component of health care regimens. Many countries legitimized complementary and alternative medicines by registering them so that their quality and safety can be controlled as their use by the public are unavoidable. However there is no way that the authority can ascertain their efficacy. Lacking the efficacy component their registration requirement is of a lesser standard than conventional medicines. Although lack of scientific and poor efficacy of complementary and alternative medicines, there is some evidence (or the only evidence for efficacy of complementary and alternative medicines) found such as the use of cranberry for urinary tract infections and St. John's Wart for depression. Most of the other claims on the effectiveness of complementary and alternative medicines are not evidence based.

Pharmacists are in an ethical dilemma in the use of complementary and alternative medicines. As health care professional pharmacist are expected to provide a high level of unbiased, evidence based health care (Applebe et al., 2002), while their business side is expected make profit. Pharmacist's professionalism and business roles are in conflict with the sale of alternative medicines. Great consideration need to be given as Pharmacists selling complementary and alternative medicines in their pharmacies will give credibility to these products and to some extent will promote their usage. Pharmacist has the responsibility to provide the factual advice for patients who seek out these products. Pharmacists can play the role in counseling for the use of complementary and alternative medicines is to ensure the health and safety of patients is not jeopardized. All counseling should adhered to the principles of evidence based medicine and honestly informing the customers of the unproven therapies but respect have to also be given to the customer's the beliefs and their autonomy to make decisions regarding their own treatment while at the same time pharmacist offer professional advice. There are cases where the complementary and alternative medicines are completely contradictory to the principles of modern medical science and a good example is the Homeopathy treatment concept. This contradiction with

all of basic medical sciences must be taken into consideration. Globally the ethical issues pharmacists face on complementary and alternative medicines are being handled appropriately according to the Code of Conduct or Code of Ethics of particular nation and based on the global perception, pharmacists is one of the most trusted health professionals.

9. Ethics in advertising

Previously, in most nations the advertising and promotion of ethical pharmaceutical products was mainly carried out for physicians and pharmacists. However from the early 1990s, companies began direct-to-consumer (DTC) advertising. DTC advertisements were used in some developed nations to inform the public that physicians had a new treatment to help them treat certain diseases. The advertisements did not mention the name of the products, but rather, they asked patients with specific problems or symptoms to see their physician for advice. This sort of DTC advertisement was quite popular in the United States. The question will be is it ethical to influence the public to ask their physician on drug prescribing.

In the middle 1990s DTC advertising in the United States went through another stage where such advertisements were allowed for magazines and newspapers where the name of the product and its indication for use are also mentioned, but such DTC advertising on television or radio only mentions either the name of the product or the indication for the product as advertisement space is limited in such media. The happening in the US led to the liberalization of drug advertisement to the general public and led the way for other nations to follow. Some small nations or developing nations are skeptical about allowing such advertisement for prescription drugs due to concerns over public perception. These nations feel that their citizens are not yet ready for such liberalization of drug advertisement.

The United State Authority has ruled that this technique of advertising can be very effective because it increases awareness among the public that a new treatment or drug is available and influences them to talk to their doctors. The Americans have now moved forward to allow DTC advertising of prescription products on the television and radio, in which advertisers can now mention both the name of the product and indications with a condition that the main precautions or warnings are also given. This has led to a revolution in the way prescription products are advertised on television.

In addition to this, advertising and promotion to physicians, seminars and symposia goes on as usual. Sales representatives are as active as ever calling on doctors, pharmacists and other health-care professionals. These representatives will give information about their companies' products, how to use them, the possible side effects and the different dosage forms available. They also give away samples to physicians and 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 give to the customers. Some nation have regulated against giving away free samples for certain categories of prescription drugs.

A number of pharmaceutical control authorities feel that pharmaceutical companies are spending too much on advertising and promotion and some even regulate the amount of revenue to be used for advertising as a form of control. The expenditure on advertisements is actually paid by the consumers as broadly advertised drugs will be more costly to the consumers.

10. Ethics in intellectual property

Broadly, intellectual property means the legality which results from intellectual activity in the industrial, scientific, literary and artistic fields (WIPO Handbook). Intellectual property law in all nations generally aims at safeguarding creators and other producers of intellectual goods and services by granting them certain time-limited rights to control the production and sales. Pharmacists and the pharmaceutical companies and organizations are very familiar with this intellectual property concept as it forms the basis of pharmaceutical invention control. If a pharmaceutical company develops a new drug, the company will enjoy the exclusive right to produce and market the product until the patent expires. This concept is known to be well respected among the pharmaceutical manufacturers. It is very unethical for a pharmaceutical product to be copied before the expiry of the patent.

There are also irresponsible companies in nations where patent law is not well respected, who will produce a copy of the product and sell the product through the black market. The pharmacist in the retail pharmacy has to be ethical not to deal with any product which has infringed the patent requirements. The authority in a nation also needs to enforce the patent law in order to be more protective of patents.

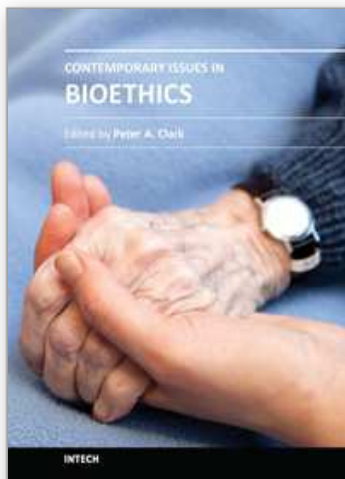
From the point of view of the patent owner, they also have to be ethical in getting profits from the patented product. We are witnessing today a global issue whereby patent owners do not totally let go of patents upon their expiry. Certain multi-national companies (MNCs) try to prolong the exclusive right to the product by re-patenting the same product with some modification. Sometimes it looks like it is well planned by the company from the beginning when the first patent was filed. The company, knowingly, first patented an inferior product formulation and then patented a superior product formulation on the expiry of the first patent and the same company enjoyed the exclusivity again. The public will then be deprived of a generic product. A good example will be a situation where a pharmaceutical company first patents a capsule dosage form (where this dosage form is quite bulky) and then patents a tablet dosage form (a smaller, more favourable dosage form) upon patent expiration with a novelty claim in terms of extra processing which is different from the normal text book technique of making tablets. This is unethical conduct since such a case can only be solved through court cases to nullify the patent and this can be very expensive. It is a serious breach of ethics and the patent authority should be more vigilant in preventing such unethical behaviour. They should seriously scrutinize the novelty or the inventive nature of the second formulation.

11. Conclusion

Ethics in the area of pharmaceuticals which concern the pharmacist as a person and the pharmaceutical company as a corporate body is experiencing evolution, where pharmacy practice is different today than it was previously. Pharmaceutical innovation and technology advancement has shaped the pharmaceutical industry and pharmacists themselves and the need of solid strong ethics to be embedded into the pharmacist as an individual which will then form the organization of pharmaceutical with high ethical values. Ethics and pharmacy at large must be sensitive and responsive to an unavoidably changing environment.

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The main strength of this book is the international exchange of ideas that will not only highlight many of these crucial bioethical issues but will strengthen the discipline of bioethics both nationally and globally. A critical exchange of ideas allows everyone to learn and benefit from the insights gained through others experiences. Analyzing and understanding real medical-ethical issues and cases and how they are resolved is the basis of education in bioethics for those who will have to make these decisions in the future. The more we examine, analyze, and debate these bioethical issues and cases, the more knowledge will be gained and hopefully, we will all gain more practical wisdom.

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