Pharmacy in Health Care System

By Siniša Franjić

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1. Introduction

The pharmaceutical industry is essentially one which supplies the community with what is known technically as “pharmaceutical products” [1]. The latter have for different purposes been defined in different ways, but for any broad discussion some of the existing definitions are likely to prove too narrow and too static.

In the broadest possible sense a pharmaceutical product, known in everyday usage simply as a “medicine” (or less accurately as a “drug”) can be defined as a substance or a complex of substances which is administered to man or to animals in order to prevent, diagnose, alleviate or cure a disease, to relieve a symptom, or to modify bodily function in some way.

Traditionally, for many centuries, pharmaceuticals largely comprised herbs or their derivatives or extracts, and less commonly materials of animal or mineral origin. At the present day, most of them are largely based on substances created in the laboratory or mixtures of such substances, only a few were obtained from the plant or animal world. In the foreseeable future, however, a fair part of the market may well be accounted for by substances or tissues prepared by genetic engineering, i.e., by a modification of biological processes in living organisms.

The definition of a pharmaceutical product used here, like some of those to be found in the national law, is also sufficiently broad to include blood products, sera, and vaccines, as well as products meant for veterinary use. It could also be considered to extend to some products used to prevent or treat diseases of plant crops (“phytopharmaceuticals”) because at some point they may enter the human system in the form of residues. Some of these groups of products have customarily been dealt with under separate legislation, but that is mainly because rather different types of expertise may be required to deal with them, or because they fall administratively under different government agencies: the legal and ethical issues relating to them are not basically different to those arising when one considers medicines of the most familiar type administered to man.

Pharmaceutical development traditionally involves a linear, sequential series of structured events [2]. This is true on both a macro (program) level as well as a micro (study) level. In both cases, there is an extraordinary amount of highly structured data - a single clinical trial alone may involve several million data points, and a development program may include as many as 30 or more studies. One of the challenging aspects of pharmaceutical development is the fact that this enormous quantity of data must be handled accurately, with accountability from the first place a result was recorded to the final database, along with each change along the way.

II. Drug

In the most general sense, a drug may be defined as any substance that brings about a change in biologic function through its chemical actions [3]. In most cases, the drug molecule interacts as an agonist (activator) or antagonist (inhibitor) with a specific target molecule that plays a regulatory role in the biologic system. This target molecule is called a receptor. In a very small number of cases, drugs are known as chemical antagonists may interact directly with other drugs, whereas a few drugs (osmotic agents) interact almost exclusively with water molecules. Drugs may be synthesized within the body (e.g., hormones) or may be chemicals not synthesized in the body (i.e., xenobiotics). Poisons are drugs that have almost exclusively harmful effects. However, Paracelsus (1493–1541) famously stated that “the dose makes the poison,” meaning that any substance can be harmful if taken in the wrong dosage. Toxins are usually defined as poisons of biologic origin, i.e., synthesized by plants or animals, in contrast to inorganic poisons such as lead and arsenic.

Safe drugs, which are consistent with new scientific principles and experience, are extremely important in treating the disease in the best and most efficient way, without the ability to bring the patient to potential danger [4]. To provide the highest possible level of patient safety, accurate and correct information should be available both to the health care team of professionals and to the patient themselves.

The permanent task of all health care professionals is to educate patients.

The most basic information about therapy, doctors and pharmacists must be given to the patients

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themselves to take an active part in their treatment, to understand the importance of the drug and to be familiar with the ability to cure and to make the therapy successful. The patient must be informed about his illness, the drug he or she is taking, his actions, the side effects, the contraindications, the interactions because the real drug is timely, accurate and objective information. The drug information must be independent, exhaustive and best in the patient's interest. The personal interests of doctors and pharmacists should not interfere with informing the patient.

Prescription and medication should not be routine, followed by silence or poorly information or with the type of instructions take this medicine twice a day. The prescribing and issuing of drugs should be individually focused on the best interest of the patient, taking into account of the specifics of each, the economic conditions in which they live, the possibilities for adequate drug use, the physical condition of the patient and numerous other factors.

III. Pharmacogenomics

Pharmacogenomics, the study of genetic factors that underlie variation in drug response, is a modern term for pharmacogenetics [5]. Pharmacogenomics implies a recognition that more than one genetic variant may contribute to variation in drug response. Historically, the field began with observations of severe adverse drug reactions in certain individuals, who were found to harbor genetic variants in drug-metabolizing enzymes. As a scientific field, pharmacogenomics has advanced rapidly since the sequencing of the human genome. In the last decade, powerful genome wide association (GWA) studies, in which hundreds of thousands of genetic variants across the genome are tested for association with drug response, led to the discovery of many other important polymorphisms that underlie variation in both therapeutic and adverse drug response. In addition to polymorphisms in genes that encode drug-metabolizing enzymes, it is now known that polymorphisms in genes that encode transporters, human leukocyte antigen (HLA) loci, cytokines, and various other proteins are also predictive of variation in therapeutic and adverse drug responses. In addition to the discoveries that have been made, the past decade has ushered in “precision medicine,” also known as “stratified or personalized medicine,” in which genetic information is used to guide drug and dosing selection for subgroups of patients or individual patients in medical practice. The Clinical Pharmacogenetics Implementation Consortium (CPIC) published a series of guidelines for using genetic information in selecting medications and in dosing. These highly informative guidelines are being used by practitioners in prescribing drugs to more effectively treat patients. Where appropriate, CPIC recommendations are included to provide information on how to use genetic variant data appropriately in therapeutic medicine.

IV. Quality Control

A pharmaceutical industry quality control laboratory has the important function of testing raw materials, packaging components, materials being processed and finished products for quality [6]. It is important to recognize that quality control plays an important role in the quality assurance of pharmaceuticals all the way from research and development on investigational medicinal products, through to scale-up and commercial manufacture. Key decisions are made from the analytical data generated, and so the reliability of the results is paramount. The safety of patients depends upon the body of knowledge generated by analytical chemists on active pharmaceutical ingredients (APIs) and drug products during product research and development, process validation studies, stability testing, in-process control and finished product testing. When problems occur, the data generated by the quality control laboratory will help to determine the cause and improve process and product quality.

Testing laboratories involved in the generation of data for product development, marketing authorization and batch release of medicinal products face the challenge of undertaking their activities in a heavily regulated environment. Also, as a functional and costly part of the business, testing laboratories must run their operations as efficiently as possible.

Regulatory authorities such as the Medicines and Healthcare products Regulatory Agency (MHRA), the Food and Drug Administration (FDA) or the European Agency for the Evaluation of Medicinal Products (EMEA) enforce national and international regulations. To comply with these, pharmaceutical companies are required to put appropriate quality systems in place. Maintaining the quality system in good working order draws heavily on resources, and costs can be high.

Regulatory compliance versus lean and efficient operational costs can be the dichotomy that every manufacturer faces.

V. Pharmacist

The law imposes duty to take care of a variety of circumstances [7]. As sellers of goods, community pharmacists must take reasonable care to warn customers of any potential dangers arising from them. Quite apart from this general duty on all vendors of goods, there is a special relationship between pharmacists and their customers in respect of transactions involving pharmaceutical knowledge. Reliance is placed upon the special skill and knowledge of the pharmacist when selling, dispensing or prescribing medicinal products. The law would expect him/her to
exercise that degree of competence which the average member of the profession is required to possess. This is known as the ‘duty of care.’ A pharmacist occupying a special position in any branch of pharmacy would be expected to have a degree of ability commensurate with that position. Pharmacists consistently, and with good reason, press for recognition as experts on drugs and medicines, and for the right to take a greater part in the health services. Every right has its correlative duty, and pharmacists, as they achieve greater recognition, must expect the law to require from them a higher degree of skill. It is probable that they will, as a consequence, be more liable to actions for professional negligence.

Years ago, the pharmacy’s main job was the dispensing and compounding of drugs [8]. Because of this relatively limited duty, ethical issues in the workplace were not as prevalent as they are today, and the law or the following of the law was the most important factor to consider. Today, in addition to dispensing and compounding medication, pharmacists counsel patients on proper medication usage, potential side effects, and drug interactions. Pharmacists also must be the mediator if and when questions arise with the patient or the prescriber. Because of the pharmacy profession’s close personal contact with the public, problems can arise, and ethical applications may need to be considered.

With high standards firmly in place and competent professionals, the pharmacy profession will continue to excel and live up to its stellar reputation. The profession has proved through changing times that it can rise to the occasion and handle ethical and legal considerations.

Pharmacy is a noble and sacred profession committed to the cause of health care for human beings [9]. The pharmacist is a vital link between the doctor and the patient. He is charged with the responsibility of providing professional services of a high order to the community at large by ensuring production of Quality Medicine and their sale and distribution to the consumers.

The pharmaceutical Ethics encompasses the code of moral principles or the science of morals which is concerned with human character. The pharmacist of today is a drub-maker, drug-dispenser, drug-custodian, patient-counselor, drug-researcher and drug-educator and above all an honest and patriotic citizen. The technoprofessional background of the pharmacist gives him/her the confidence of providing services with an ethical approach to the satisfaction of patients. The sacred values are required to be cherished and professed by the pharmacist.

VI. Pharmacy and Health Care

Pharmacy, unlike chemistry or biology, is certainly not a pure science [10]. Rather, it is a profession comprising a wide array of academic and professional disciplines that include basic sciences, business, sociology, and law. Pharmacy practice has changed as rapidly as any other profession in the past few decades. In the not so distant past, a pharmacist’s responsibilities were heavily concentrated in compounding and preparing a variety of medicinal dosage forms. A pharmacist would routinely prepare tablets, capsules, suppositories, elixirs, and other medicinal nostrums on the direction of the physician. However, as the pharmaceutical industry expanded, the more commonly compounded prescription products became commercially available. Neighborhood pharmacists were generally seen to augment physicians and became important providers of medical services. By the year 2000, pharmacists were increasingly more involved with therapeutic selection, drug regimen review and monitoring, and patient compliance through education and counseling.

During the last few decades, the pharmacist’s new role as a therapeutic advisor and overseer of drug therapy has continued to grow. The role of therapeutic advisor manifests itself primarily in the hospital setting where the opportunity to utilize medical records is presented. The drug therapy overseer role exists in the community by the patient profile that allows the pharmacist to evaluate the multiple medications that more often than not are prescribed by several different physicians. This individual is an “advocacy pharmacist.” An advocacy pharmacist assumes a truly patient-oriented role to serve the patient’s best interests.

Clinical pharmacy practitioners paved the way for the pharmacist’s advocacy role. Because they tended to work very closely with the physician and healthcare team, they prided themselves on exceedingly high professional standards and sophisticated drug knowledge. However, the world of the clinical pharmacist is in the acute care institution and academia. Today, these same precepts have crossed into all pharmacy practice in that pharmacists who practice in the advocacy model put the patient first and discuss the benefits and detriments of medications. They encourage patients to assume responsibility for their medications based on the framework of the patient’s life style, values, and environment.

Generally, a pharmacist conducts and is involved in many activities that impact and affect healthcare delivery. The principal functions of a pharmacist are preparing and dispensing of prescription medications and medical devices. Since pharmacists must be certain of the correct medication, dosage form, and directions for use before filling a prescription, a profile of a patient’s drug therapy may be crucial to assure that the medication has appropriate instructions and is used correctly. This involvement may include the use of healthcare information. Patient counseling has also become a rapidly growing function of pharmacists because of their specialized training.
These standard guidelines allow the pharmacist to practice pharmaceutical care some different practice settings. This expanded role is supported by the presence of pharmacists practicing pharmaceutical care in the acute care hospitals, ambulatory care and family practice clinics, long term care facilities, and home care programs.

However, the pharmacist of the 21st century cannot practice pharmaceutical care without an intimate knowledge of medication, pharmacy practice, and the laws and regulations that govern them. This paper no has intent to teach the practice of pharmacy. It is designed to assist pharmacists, pharmacy interns, and pharmacy technicians in the practical aspects of their daily professional activities by serving as a handy reference guide to answer fundamental questions of pharmacy practice and the law.

There is still a need to be constantly evaluating what we do and why we do it, to meet the demands of healthcare in the future [11]. There are also new challenges to be faced, such as who the knowledge managers of the future will be. The challenge in community pharmacy is probably greater: the future is likely to belong to those who are willing to develop services, take risks and then seek funding, rather than those with the common attitude of wanting money up front. Current funding mechanisms need to move away from the payment-per-dispensing-item method: greater use will need to be made of technical support and the current practice of having only one pharmacist in each shop almost certainly needs to change.

One thing is sure: whatever is developed will increasingly need to be supported by reliable evidence derived from top-quality research.

Pharmaceutical products play a central role in the prevention and treatment of disease [12]. Making safe and effective pharmaceutical products available and affordable to individuals around the world is a central challenge to the global governance system. There are however myriad obstacles to achieving and maintaining effective worldwide availability of medicines.

Even though people around the world face largely similar challenges from disease, the policy framework for promoting innovation and regulating pharmaceutical supply are remarkably disjointed. Innovation policy, insofar as it is implemented at all, is established on a country-to-country basis with minimal attention to coordination of research and development. Regulatory structures are almost equally fragmented. Each country has its own set of approval standards and regulatory procedures that must be dealt with, and only to a limited extent are there cooperative procedures or systems of mutual recognition. Corporate decisions concerning where to concentrate innovative efforts, what to produce, where to supply it and on what terms are based on the likely impact on profits and capital markets.

VII. Pharmacy and Business

In any form of business enterprise, certain rules exist to govern the behavior of the institution, and those who work in it [1]. The rules are not always clear, and they are not consistently respected, but their existence is evident and the need for some sort of standard is almost universally acknowledged. The majority of the rules are not specific to a particular type of business: they are fundamental in any enterprise because without them the business cannot operate consistently or harmoniously or play a constructive and acceptable role in serving society. These general rules concern the way in which the business operates, both internally and in its environment. Other rules, underlying and complementing these product standards, are activity-related, e.g., specific to the manufacture of goods of a particular type: it is obviously improper (but also unwise) to produce an unsafe bicycle, a glue that adheres only for a short time or a newspaper that does not attempt to tell the truth.

The pharmaceutical industry did not appear overnight [1]. It came into being over many centuries, building on traditions created by others as they served the health needs of the community in their various ways, welding those traditions together and building a new one alongside them. As makers of medicines, the industry inherited much that came from the profession of pharmacy: in its ambition to provide care and instruction for the patient it learned from the tradition of medicine: it absorbed the learning of chemistry, and it brought a dozen newer sciences to fruition. In doing so, it became a new and potent unit of society, which was all the time creating fresh knowledge on the one hand and absorbing new learning on the other, registering achievements and falling into errors, and learning from both experiences.

All these traditions, as well as those of business and industry and the growing concept of human rights in health, were progressively welded together into an industry which acquired a face, a character and a way of working of its own. These things too needed to be defined if the industry was to function as a worthy element of society, capable of enriching it but also willing to heed its needs to serve it.

VIII. Diagnosis

Disease and illness have always challenged human existence, and healthcare has mirrored humanity’s social evolution and acquisition of scientific knowledge [13]. As cities grew, populations multiplied, and long-distance travel increased, larger outbreaks of infectious diseases became possible. As our activity level, diet, and longevity have changed, we have increasingly had to treat diseases of the joints, cardiovascular diseases, and cancers. Similarly, our understanding of what causes these and other diseases
has evolved from attributing their origin to demonic forces and the imbalance of elements such as the four bodily senses of humor to today’s scientific understandings of microbiology, cell biology, and genetics. With our increased knowledge came vastly improved treatments. The days of bleeding patients to treat fevers are gone. We have vaccines to prevent infections. But as society and science have advanced, we continue to be challenged by new diseases and infections. But as society and science have advanced, we continue to be challenged by new diseases and infections. But as society and science have advanced, we continue to be challenged by new diseases and infections. But as society and science have advanced, we continue to be challenged by new diseases and infections.

Physicians usually tackle clinical situations by taking a history (asking questions), performing a physical examination, obtaining selective laboratory and imaging tests, and then formulating a diagnosis [14]. The synthesis of the history, physical examination, and imaging or laboratory tests is called the clinical database. After reaching a diagnosis, a treatment plan is usually initiated, and the patient is followed for clinical response. Rational understanding of disease and plans for treatment are best acquired by learning about the normal human processes on a basic science level: likewise, being aware of how disease alters the normal physiologic processes is also best understood on a basic science level. Pharmacology and therapeutics also require the ability to tailor the correct medication to the patient’s situation and awareness of the medication’s adverse effect profile. Sometimes, the patient has an adverse reaction to medication as the chief complaint, and the physician must be able to identify the medication as the culprit. An understanding of the underlying basic science allows for more rational analysis and medication choices.

IX. Conclusion

Each drug has its purpose, i.e., each drug is used to treat a specific disease and for other purposes should not be used. Drugs are prescribed by doctors in the form of a prescription, which should include the time to taking in of the drug to the body, the dose and the duration of the treatment. Drugs and other pharmaceutical products such as, for example, fats, creams, solutions, injections, etc. are sometimes used in the treatment of some diseases. All pharmaceutical products must be safe for use, and patients must be familiar with their healing properties. Except for doctors, real advice can be given to patients by pharmacists because, like all other medical professionals, they are active participants in health preservation. This means that activities in promoting health and disease prevention do a significant part of everyday pharmacy practice.

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