Drugs Consumer Protection in a Global Age

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Abstract *The United States food and drug laws provide the highest level of consumer protection in the world. But, instead of the huge number of legal measures taken by governments to eradicate this scourge, drugs consumer protection remains a field which still have a lot of unsolve problems, all around the world: in Europe, Asia, Afrika and so on.*

Keywords: *drugs, consumerism, consumer protection, contaminated drugs, counterfeit drugs, orphan drugs*

Introduction

Consumer protection is a general concept that involves protecting people from buying things and services that are unsafe or fraudulent. Consumer protection is one of the major social policies promoted by any modern state. Because of the importance it represents for the contemporary economy, it is an independent policy, with own objectives, priorities and tools.The speed which events follow each other today is increasingly. That's why consumerism is expanding more and more too all the sub-branches of the economy. In this way, the scope and action of consumer protection is extremely large, reaching all the economic sectors.[1]

Consumer protection and product safety include the efforts made by the government, the nonprofit organizations, businesses and individuals, to create, protect and enforce the rights of the consumers who buy products/services. While the idea of consumer protection is not new, the interest in consumer rights legislation has flourished in tandem with society's technological and economical advances. For instance, the mass commercialization of products during the industrial revolution spawned laws in the late 1890s and early 1900s regarding food purity. The rise in consumer credit, as well as the product safety awareness, stimulated the consumer protection legislation during the 1960s and 1970s.[2]

A relatively new field reached by consumer protection is those of the pharmaceutical products, more exactly, the drugs industry.

Drugs Consumer Protection in the US - a Brief History

The best known consumer protection organization in the United States is the Consumer Product Safety Commission (CPSC). The CPSC is an independent federal regulatory agency created by the Congress in 1972. Its charter is to "protect the public against unreasonable risks of injuries and deaths associated with consumer products."[3]

The CPSC has jurisdiction over about 15,000 types of products - everything from appliances to toys. The organization helps manufacturers to develop voluntary standards, to prevent accidents and injuries, to make research regarding potential product hazards and to educate consumers to choose safer products, reporting accidents and injuries related to consumer products.

[1] Csorba, L - Consumer protection in market economy, "Aurel Vlaicu" Publishing House, Arad, 2010
[2] http://law.jrank.org/pages/12503/Consumer-Protection.html
[3] http://www.faqs.org/health/topics/6/Consumer-protection.html

In addition to the CPSC, in the United States, several other agencies are responsible for protecting the public. The U.S. Department of Transportation regulates car, truck and motorcycle safety. The U.S. Department of Treasury regulates alcohol, tobacco and fire arms. The U.S. Food and Drug Administration (FDA) is responsible for the safety and efficacy (whether a product actually does what it says it does) of drugs prescription, medical devices, cosmetics and food. In the field of health care, the FDA is the major agency responsible for consumer protection.[4]

Keeping food and drugs pure and safe is an old problem, as long ago as in 1202, King John of England proclaimed a law that prohibited bread from being contaminated with any ingredients, such as ground peas or beans. In 1785, Massachusetts was the first state to pass a food adulteration law. In 1820, a group of well-known physicians met in Washington D.C. to establish the U.S. Pharmacopeia. This was a list of purity and content standards that all the drugs must meet. The U.S. Pharmacopeia still exist today. Sometimes on drug labels, consumers can see the letters USP, after the drug name. This means that the drug conforms to the standards and formulas of the U.S. Pharmacopeia.

Federal regulation of drugs began in 1848 with a law that sought to prohibit the entry of contaminated drugs into the United States. In 1862, President Lincoln established the Bureau of Chemistry, a division of the Department of Agriculture that later become the Food and Drug Administration. In the first ten years of the twentieth century, the Congress passed a series of laws to insure the purity of serums and vaccines, prohibit the interstate transport of contaminated or mislabeled food, drinks and drugs, and required federal inspection of meat packers. These laws were passed to eliminate such dangerous practices as using poisonous preservatives and dyes in meat and manufactured foods, to restrict false claims made for worthless or dangerous patent medicines.

Another aspect of consumer protection in the health field has come to prominence in the late 1990s. With the popularity of managed health care plans and the rise of for-profit health care organizations, the question has arisen over whether federal legislation is needed to establish a patient's bill rights. Such legislation would seek to strengthen consumer confidence in the health care system, by ensuring that the system is fair and responsive to the consumers' needs. In the absence of federal legislation, laws governing consumer protection in the health arena are implemented on a state-by-state basis.

The Role of FDA (Food and Drug Administration) in Protecting the US Consumers

Unfortunately, fraud in the health care industry has a major frequency. FDA cannot ensure the safety and effectiveness of products that are not FDA approved and come from unknown sources and foreign locations, or that may not have been manufactured under proper conditions. These unknowns put patient’s health at risk, if they cannot be sure of the products identity, purity and source. For these reasons, FDA recommends the consumers to obtain medicines only from legal sources.[5]

Today, the FDA's jurisdiction extends to foods, drugs, cosmetics and medical devices. These products must be proven safe and effective before they are sold in the United States. Companies wanting to sell a new food product must prove that their manufacturing process destroys harmful bacteria and adds no harmful chemicals to the food. The FDA also regulates the labeling of food and is responsible for the truth of such claims as "low fat" or "cholesterol free" on labels. Currently, naturally occurring herbal supplements do not fall under the control of the FDA. As these supplements become increasingly popular, they generate debates in the health care community about whether they should be regulated in a way similar to drugs, in order to protect consumers from contaminated products and false claims.

In the area of drugs and medical devices, the FDA requires both, animal and

[4] http://www.fda.gov/

[5] http://www.fda.gov/Drugs/DrugSafety/ucm170594.htm

human testing, before a product can be licensed and sold. Drugs and devices must not only be secure for the patients….. they must actually do what they claim to do. In other words, if a medicine claims to heal diabetes, the company intending to manufacture it must show through extensive studies that it actually does heal diabetes in most patients.

The FDA also protects people from dangerous medical devices such as x-ray machines, by setting standards of operation. It also sets standards for handling blood and other body fluid and tissues that may transmit disease.

Because the FDA requires human testing of experimental drugs before they can be licensed and sold to the public, the United States has signed the Declaration of Helsinki, a human rights document which assures that the rights of patients receiving experimental drugs are protected. The FDA enforces that all organizations testing drugs in the United States abide by the conventions of the Declaration of Helsinki. The basic provisions include:

1. Drugs should not be tested on people until they have been adequately tested on animals;
2. An independent committee, the Institutional Review Board in the United States, must approve each separate experimental study involving people;
3. People conducting the study must be scientifically qualified and approved;
4. Every participant in the study has the right to understand the expected goals, risks, benefits and potential hazards of participating in the study and may withdraw from the study at any time for any reason. This is called "informed consent";
5. The participant's privacy must be maintained in any published information arising from the study;
6. The organization performing the study must accept financial responsibility for treating any serious or unexpected problems arising from a person's participation in the study.

Drug industry is one of the most profitable branches of the world economy. From one year to another, the supply of drugs is increasingly in terms of assortment. The number of manufacturing firms is also increasing because of the high demand.

Along with them, in step with the traditional medicines so well known by the consumers, today appear increasingly on the market new drugs, both synthetic and homeopathic, most of them unknown. Are we consumers properly and fully informed regarding the consumption of these products?

Today, tens of millions of people in the United States depend on prescription of medications to sustain their health - as many as 3 billion prescriptions are written annually. Too many people, however, suffer unnecessary injuries and some die as a result of preventable medication errors. U.S. statistics show that at least one patient dies every day due to medical errors and each year about 1.3 million are in one degree or another prejudiced. These errors - in the U.S. - are ranked on the 5th place in the "top" of medical malpractice processes and lead to damage hundreds of millions of dollars, brought to the medical and pharmaceutical authorities.

In 1992, the FDA began monitoring medication error reports that are forwarded to FDA from the United States Pharmacopeia (USP) and the Institute for Safe Medication Practices (ISMP). The Agency also reviews MedWatch reports for possible medication errors. Currently, medication errors are reported to the FDA as manufacturer reports (adverse events resulting in serious injury and for which a medication error may be a component), direct contact reports (MedWatch) or reports from USP or ISMP. FDA receives medication error reports on marketed human drugs (including prescription drugs, generic drugs and over-the-counter drugs) and nonvaccine biological products and devices.

The American Hospital Association lists the following as some common types of medication errors:[6]

- incomplete patient information (not knowing about patients' allergies, other medicines

[6] http://www.fda.gov/Drugs/DrugSafety/MedicationErrors/default.htm

they are taking, previous diagnoses and lab results);

- unavailable drug information (such as lack of up-to-date warnings);
- miscommunication of drug orders, which can involve poor handwriting, confusion between drugs with similar names, misuse of zeroes and decimal points, confusion of metric and other dosing units and inappropriate abbreviations;
- lack of appropriate labeling as a drug is prepared and repackaged into smaller units;
- environmental factors, such as lighting, heat, noise and interruptions, that can distract health professionals from their medical tasks.

The Division of Medication Errors and Technical Support include a medication error prevention program staffed with pharmacists and support personnel. Among their many duties, program staff review medication error reports sent to the USP Medication Errors Reporting Program and MedWatch evaluates causality and analyze the data to provide feedback to others at FDA.

The U.S. Food and Drug Administration (FDA) believes that many of these medication-related risks are manageable if parties committed to the safe use of medications work together.

FDA and the Institute for Safe Medication Practices (ISMP) have launched a national education campaign to eliminate the use of ambiguous medical abbreviations that are frequently misinterpreted and lead to mistakes that result in patient harm. The campaign seeks to promote safe practices among those who communicate medical information.

The mission of the Safe Use Initiative is to create and facilitate public and private collaborations within the healthcare community. The goal of the Safe Use Initiative is to reduce preventable harm by identifying specific, preventable medication risks and developing, implementing and evaluating cross-sector interventions with partners who are committed to safe medication use.

Potential partners in Safe Use include: Federal agencies, Healthcare professionals and professional societies, Pharmacies, hospitals and other health care entities, patients, caregivers, consumers and their representative organizations.

In the U.S, about 10 billion dollars are spent on drugs each year. That's why, The Food and Drug Administration has prepared a list of the top 10 health frauds. These are: fraudulent arthritis products, spurious cancer clinics, bogus AIDS cures, instant weight-loss schemes, fraudulent sexual aids, quack baldness remedies or appearance modifiers, false nutritional schemes, unproven claims for the muscle stimulators and so-called cures for Candidiasis hypersensitivity.

Dishonest promoters frequently promise quick or painless cures, promote products made from a special or secret formula, present testimonials from satisfied patients, claim that their products are effective for a wide variety of ailments and claim to have the cure for disease that are not yet understood by medical science.

At the same time, the medications Guides - paper handouts that come with many prescription medicines - are another way FDA use to protect the consumers of drugs. The guides address issues that are specific to particular drugs and drug classes and contain FDA - approved information, which can help patients avoid serious adverse events.

FDA requires the Medication Guides to be issued with certain prescribed drugs and biological products, when the Agency determines that:

- certain information is necessary to prevent serious adverse effects;
- patient decision-making should be informed by information about a known serious side effect with a product;
- patient adherence to directions for the use of a product are essential to its effectiveness.

In the US, The National Council against Health Fraud can also help the public taking legal actions against such fraudulent schemes. This organization offers referral to lawyers, a registry of expert witnesses, information on defense witnesses and maintains a list of unproven, fraudulent and potentially dangerous treatments.

Drugs Consumer Protection in the European Union

According to the German periodical "Die Welt", in a survey done among a number of 127 hospital doctors, only half were able to indicate the correct dose of medications for some disease, 31% of them not being able to even suggest a dose. According to the periodical, about 25,000 patients die annually in Germany, as a result of drug dosing errors.

Drug overdose is one of the major causes of death among young people in Europe. There were almost 100,000 reported overdose deaths between 1990 and 2002 in Western Europe (EU15), with 8000 to 9000 deaths per year since 1996.

Various studies have shown that patients who visit emergency departments of hospitals or ambulatory people are often victims of medical errors.

A number of studies have emphasized that government regulation often produces undesirable or unintended side effects of the pharmaceutical industry.

The European Medicines Agency (unofficial acronym: EMA) is a European agency for the evaluation of medicinal products. From 1995 to 2004, the European Medicines Agency was known as European Agency for the Evaluation of Medicinal Products.[7]

Roughly parallel to the U.S. Food and Drug Administration (FDA), but without FDA-style centralization, the EMA was set up in 1995 with funding from the European Union and the pharmaceutical industry, as well as with indirect subsidy from the member states, in an attempt to harmonize (but not replace) the work of existing national medicine regulatory bodies.

Based in London, the EMA was born after more than seven years of negotiations among EU and replaced the Committee for Proprietary Medicinal Products and the Committee for Veterinary Medicinal Products. The EMA operates as a decentralized scientific agency of the European Union and is responsible for the protection and promotion of human and animal health. The agency is composed of the Secretariat (management board), scientific committees (one each for human, veterinary and herbal medicinal products as well as orphan drug designations) and scientific working parties. The EMA is organized into four units: human medicine, veterinary medicines and inspections, communications and networking, administration. The Management Board provides administrative oversight to the EMA: including approval of budgets and plans, selection of the executive director. The Board includes two members per member state, two from the EEC and two from the European Parliament.

To require centralized approval for eligible products, a company submits an application to obtain a marketing authorization from EMA. A single evaluation is carried out through the Committee for Medicinal Products for Human Use (CHMP) or through the Committee for Medicinal Products for Veterinary Use (CVMP). If the relevant Committee concludes that quality, safety and efficacy of the medicinal product is sufficiently proven, it adopts a positive opinion. This is sent to the European Commission to be transformed into a marketing authorization valid for the whole European Union. The EMA's Committee on Orphan Medicinal Products (COMP) administers the granting of orphan drug status. The fourth committee at EMA is the Committee on Herbal Medicinal Products (HMPC). It assists the harmonization of procedures and provisions concerning herbal medicinal products laid down in the EU Member States and further integrating herbal medicinal products in the European regulatory framework.

Since July 2007, there is a committee dealing with the new pediatric legislation in Europe (the PDCO). From July 2008, all the new applications for the marketing authorization of new pharmaceutical products have to either include data from pediatric studies (previously agreed with the PDCO), or to demonstrate that a waiver or a deferral of these studies has been obtained by the PDCO. From January 2009, this obligation

[7] http://en.wikipedia.org/wiki/European_Medicines_Agency

was extended to most variations of already authorized products (for example, for new therapeutic indications).

The majority of existing medicines throughout the European Union's member states remain authorized nationally, but the majority of genuinely novel medicines are authorized through the EMA.

The EU is currently the source of about one-third of the new drugs brought into the world market each year. But, the drugs market situation is not much better in Europe, than in the US.

Generally, there are two main types of dangerous imitations which could appear on the market:[8]

- Products resembling food - these are where a trader supplies non-edible products, which could easily be confused with food, because of their appearance, smell or texture. There have been a growing number of products being put onto the marketplace that look like foodstuffs but are not in fact edible. The EU Directive (87/357/EEC) concerns the supply of products which, appearing to be other than they are, endanger the health and safety of consumers.
- Products resembling other products – most unsafe products that are made available to resemble other products, are counterfeits. As well as being poor value for money, these can be very dangerous as they are submitted to the same rigorous safety checks as genuine products.

There are a number of products that can be confused with other products. Some traders design their products in such a way that consumers confuse them with other products. Examples include novelty lighters made to look like other products, or household items designed to look like medical products.

The most common types of products that are confused with other products are counterfeits. Counterfeiters spend money trying to copy packaging and labels in order to determine consumers to buy fake goods. Although counterfeiters spend money trying to copy genuine packaging and labels, they do not spend money on making sure that the products they sell are safe for the consumers.

China is the source of most counterfeit products and of the most counterfeit drugs on the world market, with a market out of control authorities. The increasing supply has come to worry even in the European Union, which repeatedly drew attention because these medicines present a real danger to the health of those who use them.

Things are similar for the products sold on the black market or trough online advertisements. In the case of drugs advertisements, it is possible to find fakes since their vendors rely on the fact that there will not be many consumers who will call the police or will notify the Consumer Protection organizations. Through advertisements, people can buy Viagra and other drugs to increase potency, without side effects. The Commission in Brussels warns about putting up for sale on the Internet these drugs, because most of them are not authorized by the European Medicines Agency. Indeed, it seems that at least half of the drugs sold online are "suspicious".

These are just a few reasons why, the EU officials have begun to take decisions that try to combat this phenomenon. Worried about counterfeit drugs trade size, officials of the Council of Europe have decided to organize in Strasbourg regular courses for police, tax collectors and inspectors. The consumer protection courses analysis issues that are meant to help people in fighting effectively against the import or export law of counterfeit pharmaceutical products, throughout the European Union. At present, counterfeit drugs are found in small proportion in the official market, for example, in pharmacies.

European Directorate for Quality Medicines show that counterfeiting of medicines, from their manufacture, is a serious crime that puts lives in danger and affects consumer confidence in the medical systems. That's why the Council of Europe proposes courses of training in detecting and combating drug counterfeiting, training specialists in all the EU countries.

Another way to combat this phenomenon is to help consumers to make informed choices. These days, buying prescription drugs from the Internet is easy all over the world. But to find a safe source for those

[8] www.dolceta.eu

medicines is not. More and more people are turning to the Internet for cheaper drugs that are easy to get, but medicines purchased from these Web sites often come with the risk of harming the consumers and their families. These sites use to sell drugs that are counterfeit, contaminated or simply, unsafe.[9]

By being informed about the dangers of buying drugs on the Internet, we can protect ourselves and our families from the risks posed by rogue Web sites. Over the years, the risks of buying from a rogue site don't stop at the loss of money. Lives have been lost due to people buying medicines from sites that send dangerous drugs without medical oversight that may have been tampered with, expired, or even fake.

Knowing which Web sites are safe and which ones are not, can be confusing. To help consumers making an informed choice, and as part of its mission to protect the public's health, The National Association of Boards of Pharmacy (in the US) has reviewed and continues to review, thousands of Web sites to determine if they maintain safe pharmacy practices. NABP recommends the consumers to use only sites accredited through the Verified Internet Pharmacy Practice Sites.

Drugs Consumer Protection in Nigeria - Short Overview

The National Agency for Food and Drug Administration and Control (NAFDAC) is a Nigerian government agency under the Federal Ministry of Health that is responsible for regulating and controlling the manufacture, importation, exportation, advertisement, distribution, sale and use of food, drugs, cosmetics, medical devices, chemicals and prepackaged water. The organization was formed in 1993 to checkmate illicit and counterfeit products in Nigeria, under the countries health and safety law. [10]

Contaminated and counterfeit drugs are a problem in Nigeria. In one 1989 incident, over 150 children died as a result of paracetamol syrup containing diethylene glycol. The problem of fake drugs was so severe that neighboring countries - such as Ghana and Sierra Leone - officially banned the sale of drugs foods & beverages products made in aside Nigeria.

Such problems led to the establishment of NAFDAC, with the goal of eliminating counterfeit pharmaceuticals, foods & beverages products that are not manufactured in Nigeria and to ensure that available medications are safe. That's why, in December 1992, NAFDAC's first governing council was formed. NAFDAC replaced an earlier Federal Ministry of Health body, the Directorate of Food and Drug Administration and Control, which had been deemed ineffective, partially because of a lack of laws concerning fake drugs.

NAFDAC has various basic functions. The Agency is authorized:

- to regulate and control the import, export, manufacturing, advertisement, distribution, sale and use of drugs, cosmetics, medical devices, bottled water and chemicals;
- to conduct appropriate tests and ensure compliance with standard specifications designated and approved by the council for the effective control of quality of food, drugs, cosmetics, medical devices, bottled water and chemicals;
- to undertake appropriate investigation into the production premises and raw materials for food, drugs, cosmetics, medical devices, bottled water and chemicals and to establish a relevant quality assurance system, including certification of the production sites and of the regulated products;
- to undertake inspection of imported foods, drugs, cosmetics, medical devices, bottled water and chemicals and to establish a relevant quality assurance system, including certification of the production sites and of the regulated products;
- to compile standard specifications, regulations and guidelines for the production, import, export, sale and distribution of food, drugs, cosmetics, medical devices, bottled water and chemicals;

[9] http://www.nabp.net/programs/consumer-protection/buying-medicine-online/
[10] http://en.wikipedia.org/wiki/National_Agency_for_Food_and_Drug_Administration_and_Control

- to undertake the registration of food, drugs, medical devices, bottled water and chemicals;
- to control the exportation and issue quality certification of food, drugs, medical devices, bottled water and chemicals intended for export;
- to establish and maintain relevant laboratories or other institutions in strategic areas of Nigeria, necessary for the performance of its functions.

NAFDAC has made several achievements over the years, including:[11]

- the creation of 6 Zonal and 36 state offices for easier accessibility, which are being equipped to function effectively;
- the organization of workshops to enlighten various stakeholders, such as: (a) pure water producers (b) the Patent and Proprietary Medicine Dealers Association (PPMDA) and (c) the National Union of Road Transport Workers and National Association of Road Transport Owners (NURTW & NARTO);
- raising awareness not just in Nigeria, also in other countries like India, China, Pakistan, Indonesia and Egypt;
- holding meetings, in concert with the Chairman, House Committee on Health and his members, with Ambassadors of countries identified with exporting fake drugs into Nigeria and solicited their support to stop the trend;
- making NAFDAC activities more efficient to reduce delays in - for example - registration and inspection;
- holding consultations with national and international stakeholders leading to various areas of assistance, including the areas of staff training, equipment donations and information sharing from the United States Food and Drug Agency (USFDA), Environmental and Occupational Health Science Institute (EOHSI), South African Medicines and Medical Devices regulatory Agency (SAMMDRA).

Despite the establishment of NAFDAC, the sale and use of fake drugs in Nigeria did not end.

Drugs Consumer Protection in Romania

In Romania, the issue of promoting the interests of drugs consumers is heavily disputed. Officials of the National Authority for Consumer Protection (NACP) accused - since 2007 - drug companies, that they practice unethical techniques to promote their products, going to hide their side effects and misleading advertising. The charges were launched at the World Consumer Day, with the title "Unethical promotion of medicinal products". The Romanian Association of International Medicines Manufacturers said that, the accusations of The National Authority for Consumer Protection on unethical promotion of medicines were not supportive since the rules for promoting drugs in Romania are identical to those in the EU, rated at the highest international standards of ethics. These rules were developed by the National Agency for Medicines (NAM) and the Ministry of Health since early 2001, although at that time Romania was not a member country and he not even begun the accession negotiations - sustain the Romanian Association of International Medicines Manufacturers (ARPIM). In April 2006, these rules were included in the Medicines Act (95/2006). In addition, the international pharmaceutical companies doing research and discovering new medicines joined in the ARPIM, have a code of ethics that comes to supplement the regulations developed by the NAM and the Ministry of Health. This code builds on code EFPIA (European Federation of Pharmaceutical Industries and Associations, an organization which is affiliated ARPIM), i.e., promotional activity carried out by these companies in Romania meets the same rigorous ethical standards that we observe in all the EU countries. Also, each organization receives regular checks on the topic of the international teams sent by the parent company.[12]

[11] Achievements. (2005). Retrieved on March 31, 2006, from http://www.nafdacnigeria.org/achievements.html

[12] Csorba, L - "Drugs consumer protection", Tribuna Economică review nr. 25/2010, Bucharest, Romania

Fakes and Drugs Sales

The problems facing the drug industry in Romania are complex. As the importance of prescription drugs in the Romanian health care system and national economy has increased, there has been a concomitant increase in the attention needed at the access to these pharmaceuticals. At all these problems we have to add the ignorance of the consumers in buying drugs. This clearly shows that we, consumers, are not properly and fully informed about the diverse drugs offer.

For example, all of us have used Algocalmin at least once in a lifetime. Algocalmin market in Romania is estimated at over $ 11 million annually. Low price has turned it into the pain killer no. 1 for the Romanians. Few of the consumers know, however, that the substances designed in this product can attack the links between the bones and joints, or can dissolve the calcium in the body. That's why, all the substances that exist in Algocalmin and their effects should be presented in the leaflet that accompanies the product. But what did not provide this leaflet are the reactions that occur over time and may alter the consumer's health. Even if this situation has been publicized, it has not stopped the production and sale of this product.[13]

Even if the consumers keep in their mind the health recommendations, The European Agency for the Evaluation of Medicinal Products did not restrict the use of Algocalmin. However, most European countries have banned him for many years.

In similar situation are the antibiotics which cure one or more disease, but have adverse effects on other parts of the organism.

There are medicines in whose composition are substances that are used to manufacture drugs, falling under the Romanian Law no. 143 / 2000, on drug trafficking and consumption: Codeina, Morphynum, Diazepam, Nurofen, Paracetamol Sinus etc. Their repeated use creates a highly addiction and is superfluous to mention that even in this case, in Romania does not exist an authority able to promote the consumer interests.

Under the name of ethno botanical plants- this should not be as harmfully as the traditional medicines are - market has become a billion euro business. The consumption of these legal drugs has increased in Romania four times in the last year. As a result of this consumption - many young people have suffered from personality disorders, others died after they consumed these, but no one from the competent authorities did intervene. Who is guilty of these tragedies? Not enough information? Handling consumers? Who must intervene in these cases? Who takes responsibility for the health and the life of consumers?

All the Romanian pharmacies sell not only drugs, but also cosmetics on whose label is inscribed: "Dermatologically tested." If the product has the words "Dermatologically Tested" on the packaging, it means that it has been tested on human skin. This however does not necessarily mean the product (or it's ingredients) are automatically "bunny friendly".

Take the example of self-tanning creams, which contain chemicals that protect us from sunburn, but in fact, they use chemicals which can disrupt the endocrine system and the skin cells.

Another situation where the authorities should intervene to protect consumers is establishing the drugs price. Although these products are considered to be a necessary evil, all consumers should have access to them. Unfortunately, due to the high trade margins charged by pharmacies, some people no longer afford to buy these drugs.

Another concern represents the sale on the Internet of false medicines, sales which are growing in all the EU countries. A recent survey undertaken in Romania has identified 170 fake or unauthorized drugs, distributed on the Internet. But their actual number is much higher. Most products sold in this way proved to

[13] Csorba, L - "Drugs consumer protection", Tribuna Economică review nr. 25/2010, Bucharest, Romania

be Viagra, growth hormones, sleeping pills, antibiotics, insulin and contact lenses.

In Romania, we don't have to look far to find a healthy product that's totally bogus - or a consumer who's totally unsuspecting. Promotions for fraudulent products show up daily in newspaper, magazine ads and in TV promotion campaigns.

Counterfeit drugs are "false copies" of famous brands of medicines, pharmaceutical preparations which may have similar ingredients to the original. After the investigations, the Romanian authorities detected cases with frauds were quite different ingredients were used than the original products, aggravating and not improving the patient's state which used that treatment. Some contained just chalk powder, starch or flour, but they found drugs and pills designed to mislead patients into thinking that "pills" would have a beneficial effect.

Another huge concern for the Romanian consumers is the expired drugs. That's why, regular inspections of the products and the removal of items that are within 60 days of their expiration dates, is needed. But, we can't forget to remind the consumers to check the "sell by" and "expiration" dates, and to notify the Romanian Authorities for Consumer Protection immediately if they find expired products.[14]

In Romania, both - NAM and the Ministry of Health - have specialized inspectors who work across the country to receive, verify and investigate any complaint of violation of the existing rules received from consumers, institutions, organizations or businesses. Monitoring shall be made by the Ethics Commission ARPIM. This commission is investigating the situation immediately detected and, when appropriate, punishes members who have violated professional ethics.

Are These Drugs Real? Are They Safe? Is That a Moral Sales Strategy?

All over the world, drugs consumer protection remains an idealistic issue, said Ray Moynihan[15] who, together with Alan Cassels - a pharmaceutical policy researcher - wrote a best- seller about the health care budgets which are being bankrupted by drugs industry. By examining ten disastrous drug-related cases that have jolted public trust in medicine and hugely tarnished the luster of a once admired industry, the authors underlined an ingenious marketing strategy. That strategy has succeeded in hugely increasing demand for drugs - mostly by healthy Americans.

Selling Sickness reveals how widening the boundaries of illness and lowering the threshold for treatments is creating millions of new patients and billions in new profits, in turn threatening to bankrupt health-care systems all over the world. As more and more of ordinary life becomes medicalized, the industry moves ever closer to a special dream: "selling to everyone."

The book's prologue contains the germ that sprang into action validating the authors' premise: that the pharmaceutical industry (Pharma) is no longer focused on selling cures for disease, but rather on marketing drugs to the worried well. Pharma's unprecedented profit margins attest to the power of suggestion - especially when re-enforced repeatedly through direct-to-consumer advertising. The authors use ten examples to illustrate how "the vast web of interrelationships between doctors and drug companies" and the absence of independent review, enables Pharma to achieve its goal of selling sickness to an ever widening circle of healthy people. This monolithic corporate influence has resulted in the perversion of the practice of medicine and the goal of the healing profession. Indeed, adverse drug effects are creating chronic diseases requiring additional drugs.

Moynihan and Cassels show how Pharma has used "weapons of mass seduction" to gain public trust and decisive influence over the medical profession, medical practice guidelines, public health policies and both, scientific journals and mass media. It succeeded in gaining control over medical practice and public

[14] Csorba, L - "Drugs consumer protection", Tribuna Economică review nr. 26/2010, Bucharest, Romania

[15] Moynihan, R, Cassels, A - "Selling Sickness: How the World's biggest Pharmaceutical Companies are turning us all into patients", New York, USA: Nation Books, 2005

expenditure through strategic, systematic and systemic corporate sponsorship. Indeed, this industry has succeeded in shaping our very perceptions of health and sickness to promote "lifestyle" medicines.

Pharma seems to have adopted the marketing strategy of the cosmetic industry and is creating discontent and anxiety about perceived imperfections, using psychological weapons to prey on people's fear of sickness, aging, loneliness, death - all calculated to create a demand for its latest pill. This immoral sales strategy disregards the fact that drugs have risks and adverse side effects that are often catastrophic. To overcome this problem, industry has turned medicine on its head. Instead of relying on evidence for the presence of disease and evidence a favorable risk/benefit ratio to justify a medical intervention, doctors are prescribing drugs based on corporate sponsored "public awareness" campaigns that create "illness."

"Public awareness campaigns are turning the worried well into the worried sick - underlined the authors. Mild problems are painted as serious disease, so shyness becomes a sign of social anxiety disorder and premenstrual tension a mental illness called premenstrual dysphoric disorder…… so, healthy middle aged women now have a silent bone disease called osteoporosis and fit middle-aged men a lifelong condition called high cholesterol."

Cholesterol-lowering drugs bring in revenues more than $25 billion a year.

Four of the ten cases are exclusively directed at women. The case of hormone replacement therapy (HRT) as a "treatment" for menopause, encapsulates what is fatally wrong with the marriage of convenience between doctors and industry. Science writer Barbara Seaman, co-founder of the National Women's Health Network and author of The Greatest Experiment Ever Performed on Women, is recognized as "the first prophet of the women's health movement" because she was one of the first who recognize that HRT was dangerous and for decades continued to challenge the promoters of HRT by pointing to evidence of its carcinogenicity. Somehow, Seaman was not mentioned in the book.

Selling Sickness shows how the combined effort by industry funded medical opinion leaders, PR companies, celebrities, subservient regulatory agencies, an uncritical media and a chorus of industry-supported patient "advocacy" groups have helped to promote the medicalization of "conditions" stemming from the human condition.

Selling Sickness dovetails the release of the powerful film version of John le Carre's fictionalized book, The Constant Gardner (2000). At a minimum the film raises serious questions about the immoral dumping of lethal drugs on Third World populations and the integrity of industry-sponsored clinical trials conducted in those underdeveloped countries. Both are aimed at general audiences, persuasively demonstrating how industry's control of medicine is perverting the healing profession from improving health to doing great harm.

Drug companies are systematically working to widen the very boundaries that define illness and the markets for medication grow ever larger. Mild problems are redefined as serious illness and common complaints are labeled as medical conditions requiring drug treatments. Runny noses are now allergic rhinitis, PMS has become a psychiatric disorder and hyperactive children have ADD. When it comes to conditions like high cholesterol or low bone density, being "at risk" is sold as a disease.

That' why, Selling Sickness is considered a spirited journalistic exposure of the methods used by the pharmaceutical industry to expand the market for its products. These include the redefinition of risk factors - such as raised cholesterol and blood pressure, or reduced bone mineral density - as diseases afflicting substantial sections of the society and always requiring treatment.

Conclusions

The paper suggest the present state of the approximation of laws in the EC medicinal products market and shows the deficiencies of harmonization in different areas of drug safety law (marketing authorization, post-marketing control, coordination procedures). But even where the level of legalization and approximation of laws is high, different safety decisions are taken by national authorities. The approximation of laws does not automatically produce uniform safety decisions across the European Union. Drug law can only set a

framework for consumer protection. It can't totally programme individual safety decisions.

Therefore we propose a European Medicinal Products authority which should be provided with the competence to decide on the manufacturing of new medicinal products. The consumer/patient interest in optimal drug safety should be integrated into the procedure of decision-making by a right of participation. Knowledgeable experts, authorized by consumer organizations, should be members of the advisory committee of this authority. This may be a step that would help to solve the critics on drugs safety.

But, its really possible to solve the drugs safety issues? Literature in this area is so contradictory and the market reality shows something else. There have been a lot of rumors about health care reforms. Instead of these, until every year thousands of peoples are injured by dangerous and defective drugs means that, the policy which protect the consumers' interests has proven ineffective.

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