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On Ethical Practices of Pharmaceutical Industry Stakeholders in Romania under the Pressure of Latest Legislation

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Abstract: For decades, the ethical practices of doctors, pharmacists and pharmaceutical companies, supervised by the health policies were subject for many researches. The aspects regarding the objectivity of prescribing drugs, the appropriateness of using gifts for doctors and pharmacists or the limited national budgets were proven to have great impact on patients' health. The present paper is focusing on the stakeholders' activity (doctors, pharmacists, pharmaceutical representatives and health policy makers) in Romania, under the light of latest adopted regulations.

Keywords: ethics, pharmaceutical industry, doctors, pharmacists, pharmaceutical representatives, Romania.

Introduction

The quality of life, a very frequently used concept when it is about assuring high standards for patients' health, is concerning the activity of four stakeholders: *physicians* (who undergo pressure from three sources: from decision makers for the

reduction of prescription costs, from patients for access to cutting-edge treatments, from the pharmaceutical industry, which aims at maximizing prescriptions of certain profitable molecules); *pharmaceutical representatives* (they are the first line interacting directly with healthcare professionals; they represent the most important marketing expense of a Company in the Pharmaceutical Industry); *pharmacists* (torn between the necessity to ensure quality of life for medical services and the pressure coming from their wish to stay competitive in the market); *healthcare policy decision makers* (the Ministry of Health, National Health Insurance House, Healthcare commissions. Given smaller and smaller budgets, but also the pressure of an aging population whose healthcare

expenses increase every year, decision makers undergo certain pressure - the final result must be access to cutting-edge treatments at a minimal cost). The activity of each category mentioned was subject to a lot of researches during the last decades, most of them focusing on ethics and profits (1- 4).

Research in the field suggests that healthcare professionals' attitudes to promotion vary. Some opinions suggest that pharmaceutical representatives' visits should be banned during working hours. In addition, there are varied opinions about the question whether physicians are properly trained to interact with them or not. Most healthcare professionals think that the information received from pharmaceutical companies is biased, but many of them also consider it useful. Healthcare professionals consider that small gifts from pharmaceutical companies are acceptable (5-7). Therefore, what impact does pharmaceutical promotion have on pharmaceutical industry stakeholders and on drug prescription and dispensing tendencies? So, what attitude do professionals have toward the promotion of the pharmaceutical industry? Is this attitude targeted by university curricula, in order to raise the awareness about this issue?

The physician's perspective doctors

According to the most recent Cegedim Strategic (CSD) audit data, the first 20 pharmaceutical companies (by promotional expenses) expended a total of 14.784 billion dollars in 2013 for promotional activities. These include: promotion to healthcare professionals - by pharmaceutical representatives, direct-to-consumer (DTC) advertising, professional meetings, and magazine advertising. This sum does not include the cost of samples. Moreover, it does not include the investment in e-detailing and online promotion, which, at a global level, represents one more component of promotional expenses in the pharmaceutical industry. What matters is that 77% of this sum goes toward direct interaction with healthcare professionals.

Table 1. The percentage of promotional expenses in 2013 (adapted)

| 2013 Promotional Spend Allocation of Top 20 Pharmacos | |
|---|-----|
| Total Prof'l Detailing | 68% |
| DTC | 21% |
| Prof'l Meetings | 9% |
| eDetailing | 2% |
| Journal Ads | 0% |

source: <http://pharmamkting.blogspot.ro/2014/05/promotional-spending-in-2013-of-top-20.html>

Physicians report that they use the interaction with pharmaceutical companies as a source of information about new drugs. Promotion influences attitudes more than

physicians can tell or admit. So, what impact does pharmaceutical promotion have on prescription behavior? This is the most important and the hardest research direction. People cannot be assessed on how much they are influenced by promotion and/or they are unwilling to declare it. Research clearly shows that physicians who report they rely more on information received from promotion tend to prescribe and adopt new drugs more often and faster. The evidence seems to be in favor of the influence on prescription, but more investigative research would help (8, 9). In addition, it seems that regulations which should control promotion by pharmaceutical company representatives are currently ineffective.

Many medical institutions do not have adequate policies for dealing with conflicts of interest. Regulations about the medical team's interaction with the pharmaceutical industry vary a lot from one institution to the another. There are contradictory pieces of evidence on whether this affects physicians' attitudes, and if so, whether these effects persist over time. Education about the regulation of physicians' interaction with the pharmaceutical industry seems to change attitudes and may improve physicians' abilities. On the other hand, publishing descriptions of misleading promotional methods may

lead to a change in promotion practices by drug manufacturers.

Despite the struggling of doctors in order not to be influenced by pharmaceutical companies strategies, studies are proving that subjectiveness in prescribing drugs is determined by, on the one hand, the selling strategies and, on the other hand, by the personal interest of doctor in prescribing a certain drug (7, 10).

The pharmaceutical representative's perspective

The pharmaceutical industry spends large sums of money on promotion, especially on pharmaceutical representatives, samples, mass media advertisements, as well as on sponsoring various educational events and conferences. The greatest part of these expenses (68%) goes toward the direct interaction with healthcare professionals, through pharmaceutical representatives (11-13). Promotion costs for a physician or pharmacist are substantial - in the USA, the average is over 200 USD/visit (14, 15). In Romania, there is no accurate data in scholarly literature on these aspects, but we estimate a value of ¼ of the numbers below. One should also mention that, for some physicians and pharmacists, pharmaceutical representatives are often the only

source of information about certain drugs.

Table 2. Costs per pharmaceutical representative

| View Poll Results: What is the Average Cost of a Sales Call by a Rep? | | |
|---|-----|--------|
| \$200 or less | 66 | 24.35% |
| \$201 to \$500 | 118 | 43.54% |
| \$501 to \$1000 | 55 | 20.30% |
| \$1001 to \$1500 | 10 | 3.69% |
| Greater than \$1500 | 22 | 8.12% |

source: *What Is Average Cost of Sales Call - Pharma Marketing News 2007*, <http://pharmamktng.blogspot.ro/2014/03/pharma-spends-what-on-esales.html>

Regular meetings between pharmaceutical company representatives and physicians working in medical practices and hospitals have become common; they take place daily, in many settings. These meetings occur in several forms: brief meetings during the workday or at lunchtime, lectures organized for a department/team. During these reunions, information about drugs is distributed to physicians, often being accompanied by drug samples.

These meetings often involve small gifts, such as pens, watches and calendars with the company's logo. This common practice (for non-ARPIM companies - The Romanian Association of International Medicine Manufacturers) falls within the field of ethics.

On the one hand, pharmaceutical company representatives have vast

knowledge about the drugs they promote: they can answer many questions; they offer articles and inform physicians about important aspects concerning a certain recent drug. On the other hand, while they apparently present neutral information, their main goal is to streamline the sales of their promoted drugs and to increase the probability that physicians will prescribe them.

A result of this approach is that the information provided by the pharmaceutical representative will tend to be biased, in favor of promoting the medication, overemphasizing positive effects and minimizing negative effects. Many times, psychological techniques will be used to this purpose, such as repeated exposure to the company logo or creating a sense of indebtedness in the physician's mind, after a representative has sought valuable information for the physician or has offered a free lunch.

This bias may extend to other drugs in the same therapeutic class - or, more generally, to a preference for certain therapeutic protocols. Due to the fact that representatives offer free samples, it becomes easier for a patient to be initiated into a certain type of medication.

Perhaps the most important fact is that a large part of the effects of these interactions between the

pharmaceutical industry and the physician runs at a subconscious level. When asked about their own preconceptions, physicians drastically underestimate the extent to which pharmaceutical marketing influences their own prescribing behaviors (16).

Therefore, physicians must seriously consider the scale and consequences of their cooperation with any pharmaceutical representative: the possible effect of subtle social influences on clinical decisions should be overestimated rather than underestimated; they should make efforts to obtain information about drugs from independent sources.

The number of pharmaceutical representatives at an international level has decreased over the last 10 years.

Table 3. Decrease in the number of pharmaceutical representatives, 2007-2013 (adapted)

| Year | US Sales Reps 1000s |
|------|---------------------|
| 2007 | 98 |
| 2008 | 95 |
| 2009 | 83 |
| 2010 | 78 |
| 2011 | 66 |
| 2012 | 64 |

source: <http://pharmamkting.blogspot.ro/2012/11/how-many-sales-reps-is-one-key-opinion.html>

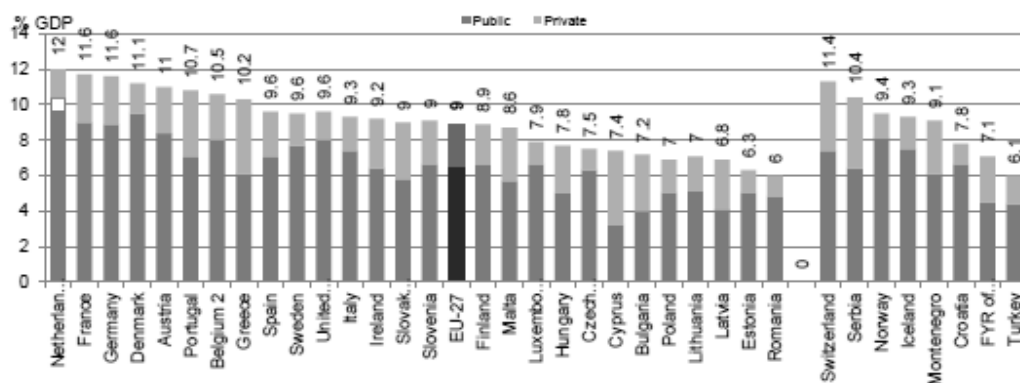
This fact is caused by the use of modern technologies (e-detailing, webinar etc.), but, to a greater extent, by the optimization of expenses caused by the loss of patents

(originators) or/and the decrease in profit margins due to falling prices (generic drug manufacturers).

Though there is no similar database for Romania, the local pharmaceutical industry complies with the same trends. Every fall in Rx drug prices practically leads to a wave of layoffs. Company budgets are yearly; for this reason, a falling price in the second half of the year may reflect in company-wide layoffs in the following January. In extreme cases, mediated layoffs may take place - entire business units may be given up.

In these circumstances, though the human resources market suffers, the industry automatically selects proficient pharmaceutical representatives, who are able to offer results to the company. From a different point of view, because of job insecurity, to satisfy company needs, pharmaceutical representatives are most prone to transgressions of ethical conduct. For this reason, organizations must have well-structured control systems and any transgression from company ethics should be sanctioned immediately; otherwise, fines resulting from possible lawsuits would seriously impact company profitability.

Total health expenditure as a share of GDP, 2010



¹ www.bnr.ro

² OECD Health Data 2010 (www.oecd.org)

Figure 1. GDP Health expenditures, 2010

source: OECD Health Statistics 2014, <http://dx.doi.org/10.1787/health-data-en>; Eurostat Statistics Database; WHO Global Health Expenditure Database

The pharmacist's perspective

The role of community pharmacists is not underestimated. Their important intervention for the community healthcare is very well - known. Even if it is about very common diseases such as influenza and headache, or a chronic disease, the community pharmacist is an important part of the medical team, assuring the recovery of the patient or assisting him in getting professional help. In some small communities, the pharmacists knows very well the pathology of each citizen and the assistance provided is very useful,

especially when it is about chronic or rare diseases. But in larger cities, assuring the profitability of a community pharmacy is a difficult task to do. Different aspects were revealed by some studies, pointed that pharmacists are subjective when it is about counseling a certain drug. Pharmacists were also subject of ethical criticism. Many studies pointed that there is a strong relationship between pharmacists and pharmaceutical representative and the quality of releasing drugs. Most of them identified no or low relation between the quality of the relationship and the quality of

prescribing and releasing drugs. For example, more frequent visits from pharmaceutical industry representatives were associated with a lower quality of prescribing (17, 18). Some other studies pointed that when they are counseling certain drugs to patients, pharmacists are influenced by the relationship between pharmacists and pharmaceutical representatives, especially when it is about community pharmacists and independent pharmacies, when profits and discounts are important aspects to survive on the market (8, 19). Also, pharmacists were identified as being a very important player when it is about prescribing *over-the-counter* drugs.

The perspective of health policy decision makers

Romania is classified by the World Bank as a smaller country of average income, with a gross domestic product (GDP) per capita of 7040 EUR in 2013, up from 5491 EUR in 2009 (20). In 2010, healthcare expenditure went up to 6% of the GDP, which is the smallest percentage of public expenditure for healthcare in the European Union, where the average is over 9%.

Pharmaceutical products represent a significant burden to healthcare budgets. Regulations controlling prescription costs and improving the quality of healthcare are being

increasingly implemented in all states, these including the use of financial incentives for prescribing physicians by increasing financial responsibility, using budgets and payments based on performance. A scholarly review of the published studies on effects in three countries (the United Kingdom, Ireland and Germany) has emphasized the fact that expenditures per item and per patient have decreased in all three countries mentioned; the published proof has revealed that generic drug consumption has increased in the United Kingdom and Ireland, but it has not provided reliable conclusions about the use of new and expensive drugs. None of the studies publishing data on the three countries mentioned above have emphasized an increase in healthcare or in effects on health. Therefore, there are some studies claiming that decreasing drug-related costs at the level of the prescriber should be obtained by diminishing the volume of prescribed drugs, by increasing the prescription of generic drugs or by both methods. Though there is a pressure on healthcare budgets in most countries, each country implements its own measures - in many cases similar, but not identical (21-26).

Regulatory measures applied in Romania

For Romania, we intend to detail three main aspects:

1. The regulation of prescription drug prices

This regulation especially refers to generic drugs. The first generic cannot be priced over 65% of the price of the originator. All generics newly introduced to the Romanian market must have the lowest price of 12 reference countries in the EU. We may deduce from this calculation that generic drug prices are more affordable in Romania than in many EU countries. On the other hand, if an original drug is approved with a certain price in Romania, its price can stay higher than in other countries if the manufacturer does not lower it according to a subsequent decrease in a different EU country. This is the reason for the revision of prices in (February-July) 2015. In principle, the regulation is efficient, but with some slippages from manufacturers, especially from originators, such products often representing the most expensive part of therapeutic protocols.

2. The claw-back tax

The claw-back tax exists in most European Union countries and it is aimed at stopping abusive consumption of drugs. Additionally - according to the initial concept - the

tax should have the role of helping small drug manufacturers in their battle with multinational companies. This tax was introduced in Romania by the Order 104/ 30.09.2009. Pharma manufacturers have repeatedly challenged the calculation method, the lack of transparency in the calculation, accusing the system of over-taxation, which includes pharmacy margins and VAT in the baseline.

According to a budget below the European average, taking into account that the list of subsidized drugs has not been updated, it would be impossible for manufacturers to finance their deficit exclusively by the claw-back tax. Pharma manufacturers estimated that they financed the healthcare system with 2.8 billion RON in 2012-2013 (declared by ARPIM in 2013).

The amount of the claw-back tax is hardly sustainable by the industry, which represents over 400 million EUR per year (calculated for 2011 - Ed.), an average of 33.6% of total subsidized drug sales, higher than the taxes of any company, unique throughout Europe in this form. In addition, another aspect worth mentioning is the lack of an updated list of reimbursed drugs: these lists have not been updated between 2008 and 2014.

Over 110 new molecules/ indications covering a total of 12 therapeutic areas with a strong impact on society in what concerns morbidity, disability and mortality (oncology, cardiology, rheumatology, diabetes, etc.) have been assessed in a study carried out by the Institute of Economic Forecasting within the Romanian Academy, with the support of the Local American Working Group (LAWG). The study concludes that the long-term economic benefits of updating the lists are five times higher than the costs (27). Finally, between November 2014 and July 2015, approximately 50 new molecules were introduced after a complete revision of the list of subsidized drugs. The complete list of molecules to be introduced is around 150. With this revision, following an assessment of the cost/efficiency ratio, some molecules were removed from the list of subsidized drugs.

3. Regulations on healthcare professionals' sponsorships by the pharmaceutical industry

According to the Emergency Ordinance (GEO) 2/2014, approved by the Government and published in the Official Journal of Romania, physicians' sponsorships by the pharmaceutical industry have been regulated. Thus, manufacturers and vendors in the pharmaceutical industry have the obligation to

declare their sponsorship activities for employees in the medical system to the Ministry of Health and the National Agency for Medicines and Medical Devices. Article 127 of GEO 2/2014, states that "Manufacturers, market authorization holders or their representatives in Romania and wholesale and retail distributors of medication, medical devices and sanitary supplies have the obligation to declare to the Ministry of Health and the National Agency for Medicines and Medical Devices all their sponsorship activities, as well as any other expenses covered by them for physicians, nurses, professional organizations, patient organizations and any other type of organizations with healthcare activities" (28). The big steps related to the legislative changes were (ARPIM - Transparency between the industry and PSS RO-CP - from 2012 to 2016 - adapted):

- Board of EFPIA approves the pre-form of EFPIA Code modifications (15 of February 2013)
- General Assembly of EFPIA adopts the final form of EFPIA Code (24-25 of June 2013)
- General Assembly of ARPIM adopts the Transparency Code (31 of December 2013)
- Each company member provides data (2015)
- The obligation for Pharmaceutical Industry to publish the collected data (2016)

As showed above, professional organizations voluntarily proposed these changes starting from 2012, the legislative change being, in fact, a confirmation of the necessity of introducing such measures. As previously mentioned, there is a need for an orientation guide evaluating the impact of the close connection between the physician and the “commercial market”, determined by insidious means of influence.

Conclusions

Hereby we have some outstanding conclusions regarding ethical practices of pharmaceutical industry stakeholders:

- Physicians community must raise the awareness regarding exposure to the pharmaceutical industry influence, therefore from early stages of professional development - internship or even from faculty should be actively trained for the ethical interaction with medical representatives,
- Pharmacists community must implement by themselves/or with the intervention of health policy decision makers more strict guidelines regarding ethical counseling of patients for OTC drugs and medical supplements due to the fact that this category of products are the one that can sustain a profitability of the business - Rx prices and the

marginal profit being constantly decreased,

- The health policy decision makers must balance between a low budget and the bioethical principles as (social) justice based on what every person needs to be treated equally, regardless of social status, economic status, race, gender, marital status, religious belief of the patient,
- Regulation of prescription drug prices is mandatory in to balance between the needs of an ageing population and a low healthcare budget. Nevertheless it has to be a careful process, due to fact that a very low price of a drug in a certain country, can have a rebound effect favoring the parallel export - and in this case the patients' access to the prescription drug in that specific country is paradoxally diminished by the low price,
- The health policy decision makers must consider the claw back tax calculation a constant process which has to be periodically revised based on healthy economic calculation. Representatives of pharmaceutical industry must be involved to ensure a transparency of the process,
- The professional organizations of the pharmaceutical industry has undertaken the necessary steps regarding regulation of the

connection between the healthcare professionals and the “commercial market”, nevertheless a higher control of implementation is needed especially for pharma companies which are not affiliated to EFPIA/ARPIM structures and where ethical slippages are possible.

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