STUDIA UBB BIOETHICA, LX, 2, 2015 (p.11-20)
(RECOMMENDED CITATION)

ETHICAL ISSUES IN DRUG PRESCRIBING PRACTICES IN ROMANIA. OPINIONS OF THE PHARMACEUTICAL REPRESENTATIVES

MAGDALENA IORGA[1], LASZLO-ZOLTAN SZTANKOVSZKY[2*], CAMELIA SOPONARU[3], BEATRICE-GABRIELA IOAN[4]

REZUMAT. Probleme etice în practicile prescrierii medicamentelor în România. Opinii ale reprezentanţilor farmaceutici. Studiul are ca scop identificarea opiniilor reprezentanţilor farmaceutici cu privire la practicile prescrierii medicamentelor de către medici în România. *Material şi metodă*: un număr de 70 de reprezentanţi farmaceutici care lucrează la diferite companii farmaceutice din România au răspuns la un chestionar privind practicile de prescriere a medicamentelor de către medici. Variabilele ca vârstă, sex, educaţie medical/non-medicală, experienţa de lucru sau mediul de lucru au fost luate în consideraţie. Datele culese au fost prelucrate cu Statistical Package for Social Sciences (SPSS) versiunea 17.0 pentru Windows. *Rezultate*: 95% dintre subiecţi apreciază că medicii îşi folosesc experienţa cu un anumit medicament atunci când îl prescriu. Un număr de 67% dintre reprezentanţii farmaceutici consideră că medicii îşi acoperă costurile activităţilor legate de educaţia medicală continuă şi training prin sponsorizări oferite de către companiile farmaceutice. 66% dintre participanţi apreciază că relaţiile medicilor cu reprezentanţii medicali sunt importante atunci când prescriu medicamente. *Concluzii*: Reprezentanţii farmaceutici consideră că practicile de prescriere a medicamentelor de către medici sunt influenţate de mai mulţi factori legaţi de politicile de sănătate sau criterii personale, inclusiv relaţiile dintre medici şi reprezentanţii farmaceutici.

***Cuvinte-cheie**: etică, reprezentant farmaceutic, prescrierea de medicamente, medic.*

[1] *PhD lecturer, psychologist, Department of Behavioral Sciences, "Gr. T. Popa" University of Medicine and Pharmacy, Iasi, Romania, email: magdalena.iorga@umfiasi.ro*

[2] *PhD student, MD, Department of Behavioral Sciences, "Gr. T. Popa" University of Medicine and Pharmacy, Iasi, Romania*

** Corresponding Author: sztankovszky@yahoo.com*

[3] *PhD, psychologist, associated professor, "Al. I. Cuza" University of Iasi, Romania, email: puzdriac@yahoo.com*

[4] *PhD, MD, associated professor, "Gr.T.Popa" University of Medicine and Pharmacy, Iasi, Romania, email: ioanbml@yahoo.com*

ABSTRACT. The study aims at identifying the opinion of pharmaceutical representatives about drug prescribing practices by physicians in Romania. *Material and methods:* a number of 70 pharmaceutical representatives working with different pharmaceutical companies in Romania answered a questionnaire concerning drug prescribing practices by physicians. Variables like age, medical/nonmedical education, and work experience or work environment were taken into consideration. Data were processed by Statistical Package for Social Sciences (SPSS) version 17.0 for Windows. *Results*: 95% of the subjects appreciate that physicians use their experience with a particular drug when they prescribing it. A total of 67% of pharmaceutical representatives think that physicians cover the costs of activities related to their continuing education and training by sponsorships offered by the pharmaceutical companies. 66% of the participants claim that the physician's relationship with the medical representative is important when prescribing drugs. *Conclusion*: the pharmaceutical representatives are considering that drug prescribing practices by physicians are influenced by several factors, related to health policies or personal criteria, including the relationship between the physician and the pharmaceutical representative.

Keywords*: ethics, pharmaceutical representative, drug prescription, physician.*

1. Introduction

The interactions between the physicians and the pharmaceutical representatives were largely detailed in the scientific literature in order to identify to what extent the relationship between them influence the drug prescribing process.

The interaction begins in the medical school and continues with a rate of 4, 4 meetings per month (Wazana, 2000) but recent studies show that this rate is even higher (Campbell, 2007 a b). Other studies show that 80-95% of physicians meet pharmaceutical representatives regularly and the increase in prescribing a drug can be observed in the next 6 months after attending a sponsored conference. It is also estimated that, in United States, for examples, approximately 21.000 dollars are spent yearly by the pharmaceutical companies for each physician (Breen, 2004).

Despite the fact that physicians declare that they are not influenced by their relationship with the pharmaceutical representatives, or that this interaction can influence to a little extent their objectivity when prescribing drugs (Chimonas, 2007), the tools used by the pharmaceutical representatives are being declared as accepted and appreciated (gifts, financial support for the continuing educations, touristic packages, sponsorships for the employing institution, invited speaker, samples or participation in clinical trials) and the analysis of the physicians' behaviour is proving that prescribing costs are increasing (Caudill et al, 1996).

Many studies showed that the physician-pharmaceutical representative relationship influence the drug prescribing process. Previous studies identified that patient's prescription is finally the result of physician-pharmacist-pharmaceutical representative interaction (Iorga et al, 2015; Sztankovszky et al, 2015, a2015b, 2015c). However professional behaviour must be guided by education and policy rules.

The goal of our study was to identify the opinions of the pharmaceutical representatives about drug prescribing practices by physicians in Romania and to appreciate in what extent they use different tools to promote their products to physicians.

2. Material and Methods

A number of 70 pharmaceutical representatives working for different pharmaceutical companies and located in 14 county seats in Romania agreed to participate in the survey. The work area covers approximately 75% of the country, taking into account that each pharmaceutical representative may conduct business in a maximum of 4 counties. The survey was conducted between January and May 2015.

The printed questionnaires were accompanied by the informed consent paper, explaining to the participants the purpose of the survey, guaranteeing confidentiality of personal data and the method for dissemination of study results. The option not to take part in the study was granted to all subjects. The research was approved by the Research Ethics Committee of the "Gr. T. Popa" University of Medicine and Pharmacy in Iaşi and it is a part of a larger research having the objective to identify the opinion of pharmaceutical representatives about practices of promoting, prescribing and dispensing drugs in Romania.

The questionnaire was designed to identify the opinion of pharmaceutical representatives about the drug prescribing practices in Romania and it covers 7 dimensions detailed below.

Dimension 1- Criteria used by physicians when prescribing treatment: Item 1: personal experience with a certain molecule, Item 2: clinical observations throughout their professional path, practical results, Item 3: meta-analyses related to the given drug, published in meaningful journals, Item 4: the innovative character of the given drug, recent scientific information, Item 5: the standard treatment protocol for the given diagnosis.

Dimension 2- Means by which physicians cover the costs of their continuing education and training: Item 1: sponsorships from the pharmaceutical industry, Item 2: sponsorships from the employing institution, Item 3: sponsorships

from national and international projects and grants, Item 4: financial self-support (personal resources).

Dimension 3- The influence of health policies and the patient's possibilities of financial contribution on drug prescribing: Item 1: the patient's financial contribution, Item 2: budgetary limitations imposed by the National Health Insurance House, Item 3: availability of the drug in local pharmacies.

Dimension 4- The physician's relationship with the pharmaceutical representative.

Dimension 5- Complementing the treatment of the given pathology with over-the-counter (OTC) products and supplements.

Dimension 6- Using international non-proprietary names (INNs) when prescribing drugs.

Dimension 7- Recommending the brand name product along with the INN.

The items were multiple choice, with answer options on a scale of 1 to 4, where 1 – *never*, 2 – *sometimes*, 3 – *often*, 4 – *always*.

The collected data were processed by means of the statistical processing software SPSS (Statistical Package for Social Sciences) version 17.0 for Windows.

The following types of statistical methods were used:

- Descriptive statistics, which pursued the central tendency and dispersion indicators (the mean and standard deviation).
- Comparative statistics- the Mann-Whitney test for nonparametric data, for independent samples was used due to the testing of the difference between independent groups of pharmacists, for which the dependent variable was expressed in ordinal (ranking) values.
- Correlational study, aimed at identifying the various correlations between independent and dependent variables, by calculating Spearman's correlation coefficient (correlations being significant at an accepted significance threshold $p < 0.05$). Spearman's coefficient is used because nonparametric data is involved.

The independent variables (age, duration of employment, gender, category, medical/nonmedical university education) influence the dependent variables taken into account: the collaborative relationship with the physician (using informal gifts- flowers, chocolate; samples; sponsorship for physicians for the purpose of continuing medical education or for the medical institutions, other informal sponsorships; participations in clinical studies, market research and observational studies).

The age of the participants was in the range 25-48 years, with an M of 35.44 ± 5.89 years.

The share of female and male pharmaceutical representatives was balanced: 34 participants (48.57%) were male (age M= 37.20 ± 5.81) and 36, representing 51.43%, were female (age M = 33.77 ± 5.54). Work experience ranges

from 1 to 27 years, with M = 11.60 ± 5.76.The minimum length of employment as a pharmaceutical representative declared was 1 year and the maximum was 18 years, with M = 8.02 ± 4.56. There are no major differences in the length of employment variable between genders.

A total of 56 pharmaceutical representatives (80% of the participants) work in urban environments, 5 participants (7.14%) work in rural environments and 9 participants (12.86%) carry out the promotion of products of their employing companies both in urban and in rural environments.

Of the 70 pharmaceutical representatives included in this study, 41 (58.57%) have medical studies (General Medicine or Pharmacy) and 39 subjects (41.43%) graduated from non-medical faculties.

A number of 28 men (40%) and 28 women (40%) work as pharmaceutical representatives in urban environments; 1 man (1.43%) and 4 women (5.71%) work in rural environments; the subjects who carry out their professional activity both in rural and in urban areas are 5 men, representing 7.14%, and 4 women (5.71%).

3. Results and Discussions

The pharmaceutical representatives have answered seven questions concerning drug prescribing practices by physicians and other aspects related to their activity.

1**.** The analysis of the answers to the question: *How frequently do you consider that the physician applies the following criteria in prescribing treatment* showed that:

a. Experience with a particular molecule: 2.9% (N = 2) never, 1.4% (N = 1) rarely, 51.4% (N = 36) often, 44.3% (N = 31) always, with a mean value of M = 3.37 ± 0.66.

b. Clinical observations throughout the career path and practical results: 1.4% (N = 1) never, 10% (N = 7) rarely, 58.6% (N = 41) often, 44.3% (N = 31) always, with M = 3.17 ± 0.65.

c. Meta-analyses related to the given treatment, published in scientific journals: 8.6% (N = 6) never, 47.1% (N = 33) rarely, 32.9% (N = 23) often, 11.4% (N = 8) always, with M = 2.47 ± 0.81.

d. Scientific information/reading about the latest research in the given field: 12.9% (N = 9) never, 37.1% (N = 26) rarely, 34.3% (N = 24) often, 15.7% (N = 11) always, with M = 2.52 ± 0.91.

e. The standard treatment protocol for the given diagnosis: 5.7% (N = 4) never, 14.3% (N = 10) rarely, 51.4% (N = 36) often, 28.6% (N = 20) always, with M = 3.02 ± 0.81.

Pharmaceutical representatives believe that, in 95% of cases, physicians apply their experience with a particular drug as a prescribing criteria.

From the analysis of results, we identify the fact that, according to pharmaceutical representatives, 78% of physicians primarily take into account the standard treatment protocol for a given diagnosis. In order of importance, we identify the experience with a particular molecule, the standard treatment protocol, clinical observations, information obtained from recent research and, lastly, meta-analyses published in scientific journals.

2. To the question which aims to identify the pharmaceutical representative's opinion regarding *ways in which the physicians pay the costs of their continuing education and training*, the participants answered the following:

a. By sponsorships from the pharmaceutical industry: 14.29% (N = 10) of the participants consider that the physicians never pay for their continuing education by sponsorships from the pharmaceutical industry, 18.57% (N = 13) think that this rarely happens, 48.57% (N = 34) consider that this often happens and 18.57% (N = 13) consider that physicians always pay the costs of their continuing education by sponsorships from the pharmaceutical industry (M = 2.71 ± 0.93).

b. By sponsorships from the employing institution, with M = 2.02 ± 0.90, a percentage of 32.86% (N = 23) of pharmaceutical representatives think that physicians never pay the costs of their continuing education by sponsorships from the employing company, 37.14% (N = 26) claim they rarely do so, 24.29% (N = 17) often, 5.71% (N = 4) claim that physicians always pay the costs of their continuing education by sponsorships from the employing company.

c. By sponsorships from grants or national/international projects, with M = 2.24 ± 0.90, a percentage of 20% (N = 14) of pharmaceutical representatives believe that physicians never pay the costs of their continuing education by financial resources obtained through projects or grants, 47.14% (N = 33) claim that they rarely do so, 21.43% (N = 15) believe they often do so and 11.43% (N = 8) claim that physicians always pay the costs of their continuing education and training by sponsoring from national or international projects and grants.

d. Paying the costs of continuing education and training from personal financial resources, with M = 2.67 ± 0.97, a percentage of 12.86% (N = 9) of pharmaceutical representatives estimate that physicians never pay the costs of their continuing education by personal resources, 30% (N = 21) claim they rarely do so, 34.29% (N = 24) declare they often do so and 22.86% (N = 16) of pharmaceutical company representatives believe that physicians always pay the

costs of their continuing education from personal financial resources. A total of 67% of pharmaceutical representatives think that physicians pay the costs of activities related to their continuing education and training by sponsorships from pharmaceutical companies.

Aproximatly56% estimate that physicians frequently pay for their participation in courses and trainings from personal funds, while the other sources are, to a lesser extent, funds obtained from national or international projects and grants and assistance from the employing institution.

Thus, in the opinion of pharmaceutical representatives, physicians pay for their continuing education and training by the following means, in the decreasing order frequency: sponsorships from pharmaceutical companies, personal financial resources, financial resources from national/international projects/grants, sponsorships from the employing institution

3. The third question followed pharmaceutical representatives' opinion of physicians' treatment prescribing practices, assessing to what extent the physician takes into account the patient's financial contribution (M = 2.90 ± 0.81) when establishing the treatment, to what extent the physician takes into account the budgetary limitations by the *National Health Insurance House* (*NHIH*) with M = 3.08 ± 0.79, or the availability of the prescribed drug in the local pharmacies (M = 2.68 ± 0.97). The distribution of pharmacists' answers to this question is detailed in the table below:

When prescribing treatment, the physician takes into account:	Never N (%)	Rarely N (%)	Often N (%)	Always N (%)
The patient's financial contribution	6 (8.57%)	9 (12.86%)	41 (58.57%)	14 (20%)
Budgetary limitations of the National Health Insurance House	2 (2.88%)	13 (18.57%)	32 (45.71%)	23 (32.88%)
Drug availability in local pharmacies	8 (11.43%)	23 (32.88%)	22 (31.45%)	17 (24.29%)

The data in the table above show that the pharmaceutical representatives consider that when prescribing a drug the physicians take into account (in the decreasing order of frequency): the budgetary limitations of the National Health Insurance House, the patient's financial contribution, the availability of a drug in local pharmacies.

4. Concerning the question *When prescribing a particular drug, is the physician's relationship with the pharmaceutical representative important?*, the participants' answers (M = 3.04 ± 0.84) are the following: 5 of them (7.14%) consider that the physician's relationship with the pharmaceutical company representative is never important, 9 participants (11.43%) claim that this is rarely important when prescribing a drug, 36 participants (51.43%) appreciate that the relationship between the physician and the pharmaceutical representative is often important and 21 of them (30%) consider that this relationship is always important when prescribing a drug. 66% of the participants consider that the physician's relationship with the medical representative is important when prescribing drugs.

5. To the question concerning *the physician's practices of recommending over-the-counter (OTC) products and supplements in addition to the treatment of the given pathology*, the average of answers is 2.77 ± 0.59. 22 participants (31.43%) estimate that physicians rarely recommend these products, while most of the participants- 42 (60%)-consider that the physicians often do so and 6 (8.57%) always supplement the established medication for the given diagnosis with additional products – OTC and supplements.

In pharmaceutical representatives' opinion, over 60% of physicians often recommend over-the counter products and supplements to complement a patient's recommended treatment.

6. Concerning the question aimed at the participants' opinions about *physician's use of international non-proprietary names (INNs) in prescriptions*, 2 pharmaceutical representatives (2.86%) think that physicians rarely do this, 45 (64.29%) think they often prescribe INN and 23 (32.86%) claim that physicians always prescribe INN subjects (M = 3.30 ± 0.52).The results show that 96% of the participants consider that physicians prescribe INNs.

7. The seventh question aims at identifying pharmaceutical representatives' opinion regarding *physicians' practices of prescribing INNs, but also recommending the brand name product.* The statistical analysis of the answers (M = 2.91 ± 0.67) highlighted the fact that 2 (2.86%) pharmaceutical representatives estimate that physicians do not recommend the brand name product as well when prescribing treatment, 13 (18.57%) consider that physicians rarely recommend the brand name product too, 44 (62.86%) mention that physicians often provide this additional information and 11 (15.7%) of them consider that physicians always recommend the brand name product too. According to pharmaceutical representatives, 60% of physicians recommend the brand name product as well when prescribing treatment.

4. Conclusions

Our study showed that according to the opinions of the pharmaceutical representatives, physicians use mainly their experience with a particular drug as prescribing criteria. Nonetheless physicians pay for the activities related to their continuing education and training by sponsorships from pharmaceutical companies and the relationship between the physicians and pharmaceutical representatives is important to the drug prescribing practices. Many physicians often recommend *over-the counter* products and supplements to complement a patient's recommended treatment and the majority of pharmaceutical representatives consider that physicians write prescriptions with international non-proprietary names. Also the participants consider that more than a half of the physicians recommend the brand name product as well when prescribing treatment.

Our findings prove that prescribing drug is a process influenced by a many factors, among them we can name physician-pharmaceutical representative relationship, personal experience with a drug, the health policies related to the patients' financial possibilities. The research proves that prescribing drug practices in Romania is not entirely objective and that the official rules must be taken into consideration when dilemmatic situations occur.

REFERENCES

Breen, K. J. (2004). The Medical Profession and the Pharmaceutical Industry: When Will We Open Our Eyes? *Medical Journal of Australia*, 180(8), 409-410.

Campbell, E. G., Gruen, R. L., Mountford, J., Miller, L. G., Cleary, P. D., Blumenthal, D. (2007). A National Survey of Physician - Industry Relationships. *New England Journal of Medicine*, 356(17), 1742-1750.

Caudill, T. S., Johnson, M. S., Rich, E. C., McKinney, W. P. (1996). Physicians, Pharmaceutical Sales Representatives, and the Cost of Prescribing. *Archives of Family Medicine*, 5(4), 201.

Chimonas, S., Brennan, T. A., Rothman, D. J. (2007). Physicians and Drug Representatives: Exploring the Dynamics of the Relationship. *Journal of General Internal Medicine*, 22(2), 184-190.

Fugh-Berman, A., Ahari, S. (2007). Following the Script: How Drug Representatives Make Friends and Influence Physicians. *PLoS Medicine*, 4(4), 621.

Iorga, M., Sztankovszky, L.Z., C Soponaru, C., Gardikiotis, I. (2015). Pharmacists' Attitude and Practices about Drug Dispensing in Romania. *FARMACIA, 63 (4):* 601-606.

Komesaroff, P. A., Kerridge, I. H. (2002). Ethical Issues Concerning the Relationships between Medical Practitioners and the Pharmaceutical Industry. *Medical Journal of Australia*, *176*(3), 118-122.

Sztankovszky, L. Z., Iorga, M., Gheonea, C., Russu, G. (2015a). The Ethics of Prescribing off-Label Drugs in Children. The Dilemma of Sildenafil. *Romanian Journal of Paediatrics*, *64(2*): 126-130.

Sztankovszky, L. Z., Iorga, M., Soponaru, C., Astărăstoae, V. (2015b). Pharmacists' Perception of Physicians' Practices of Drug Prescription, Rev *Med Chir Soc Med Nat Iasi*, *119 (3):* 873-878.

Sztankovszky, L. Z., Soponaru, C., Iorga, M., Astărăstoae, V. (2015c). Pharmacists' and Physicians' Perception of Pharmaceutical Representative's Ethical Practices of Drug Promotion in Romania. A Comparative Study. *Postmodern Openings, 7(1):* 189-199.

Wazana, A. (2000). Physicians and the Pharmaceutical Industry: is a Gift Ever Just a Gift? *Jama*, 283(3), 373-380.