

THE TRIANGLE PHYSICIAN-PHARMACIST-PHARMACEUTICAL REPRESENTATIVE IN THE PRESCRIBING-PROMOTING- DISPENSING DRUG PROCESS – ETHICAL ISSUES

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REZUMAT. Triunghiul Medic-Farmacist-Reprezentant farmaceutic în procesul de prescriere-promovare-distribuire a medicamentelor – Probleme etice. Studiul evidențiază modalitatea în care reprezentanții companiilor farmaceutice, medicii și farmaciștii din farmaciile comunitare respectă următoarele principii etice: principiul autonomiei, principiul binefacerii, principiul dreptății și principiul justiției sociale, cu scopul de a asigura calitatea vieții pacienților. Lucrarea prezintă, de asemenea, câteva concluzii generale cu privire la procesul de promovare-prescriere-eliberare a medicamentelor, punând în evidență cele mai importante riscuri și propune acțiuni de limitare a consecințelor negative. Calitatea vieții pacientului trebuie să primeze, atât în cazul celor implicați în politicile de sănătate, cât și în activitatea desfășurată de cele trei părți interesate (reprezentanții farmaceutici, medicii și farmaciștii) care trebuie să asigure sănătatea pacienților.

Cuvinte-cheie: etică, industria farmaceutică, pacient, calitatea vieții, politici de sănătate.

ABSTRACT. The research highlights the way in which, within the activity of drug promotion, prescribing and dispensing, pharmaceutical company representatives, physicians and pharmacists in community pharmacies respect the following ethical principles: autonomy, beneficence, fairness, and social justice in order to assure the quality of life for the patients. The paper presents also some general conclusions regarding the promotion-prescribing-dispensing drug process pointing the main risks and also proposes some actions for limiting the negative

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consequences. The patients' quality of life must come first, for the main three stakeholders (pharmaceutical representatives, doctors and pharmacists) and also for the policy health makers.

Keywords: *ethics, pharmaceutical industry, patient, quality of life, healthcare policy.*

1. Introduction

Patient's satisfaction was always a health care quality metric. Related to this, expenditures and healthcare policies were applied all over the world. Patient's benefits and pharmaceutical companies' profits are not always on the bright side and healthcare policies are meant to guide the process of promoting-prescribing-dispensing drugs in order to assure patient's satisfaction (Fenton *et al*, 2012) and healthcare policies are oriented now to eliminate the waste in health care system (Brody 2010; Berwick& Hackbarth, 2012; Brody 2012; Cassel & Guest, 2012).

Previous research proved that the main 3 stakeholders (pharmaceutical representatives, doctors and pharmacists) are guided by ethical principles but sometimes other subjective factors are influencing their activities (Sztankovszky *et al*, 2015a, 2015b) and differences of opinion between them are influencing the patient's care process (Iorga *et al*, 2015a, 2015b, Sztankovszky *et al*, 2016a, 2016b).

The research analyzed the way in which, within the activity of drug promotion, prescribing and dispensing, pharmaceutical company representatives, physicians and pharmacists in community pharmacies respect the following ethical principles: autonomy, beneficence, fairness, and social justice in order to assure the quality of life for the patients and explain the results to present the current situation in Romania. The main conclusion is that the patients' quality of life must come first, for the main three stakeholders (doctors, pharmacists and pharmaceutical representatives) and also for the policy health makers.

2. Material and Methods

To this purpose, following the content analysis of the focus groups organized with physicians, pharmacists, pharmaceutical representatives and the mixed group, the dimensions defining the ethical universe of drug promotion, prescribing and dispensing practices were delineated and we set up three questionnaires which emphasized, for each of the 3 target groups, self-perception and hetero-perception concerning these practices.

The mirroring construction of the questionnaires has taken into account the attempt to accurately identify differences of opinion between the

three batches investigated. Though they work together and their activities are complementary with the purpose of ensuring high quality medical services for patients, the results prove that there is obviously a communication niche, especially between pharmacists and the other two medical categories.

In total, 419 subjects from 25 Romanian counties participated in the research: 200 doctors (47.73%), 149 pharmacists (35.56%) and 70 pharmaceutical representatives (16.71%) with the mean age 40 ± 10.48 (minimum age 24 and maximum age 73). A number of 119 subjects are men (28,40%) and 300 are women (71,60%).

The research was approved by the ethical committee of the University of Medicine and Pharmacy „Gr.T.Popa” of Iasi and was conducted during a period of 5 months. Data have been analyzed using SPSS 17 for Windows.

3. Results and Discussions

The research pointed some important differences regarding the opinions of the three stakeholders. The results are generating more dilemmas and we present some interpretations in order to explain them.

Limiting Factors in the Process of Drug Prescribing

Though, from an ethical viewpoint, patients must benefit from the best treatment for their condition, according to the result of the Physicians' Questionnaire, in more than 50% of cases, physicians are influenced by different aspects when they prescribe a treatment. In prescribing the treatment, physicians take into account other criteria beside the drug considered the most appropriate, such as:

- a. the patient's financial resources,
- b. health policies – budgetary limitations established by the National Health Insurance House,
- c. aspects linked to proximity, to the existence of a certain drug in the given area.

In connection with this problem – the patient's financial contribution – we note that 70% of physicians consider that, in counseling a patient, the pharmacist takes into account his **financial contribution** – this being a more important factor, as they notice directly the patient's resources for purchasing or not a treatment prescribed by the physician.

From the analysis of answers given to the same item addressed to community pharmacists, we observed that 80% of pharmacists take into account the patient's financial resources when dispensing a prescription.

In their turn, health policies, by limitations imposed by the National Health Insurance House (NHIH), influence the drug prescribing and dispensing chain. As the NHIH imposes the prescription of drugs by International Nonproprietary Names, the individualization of treatment is influenced; it is a known fact that, given biological individuality, the individualization of treatment for each patient is important for the final outcome.

Displacement of the Decision to Dispense an INN Drug

Over 80% of doctors prescribe International Nonproprietary Name (INN) drugs (though over 40% also/only mention INNs). Comparing the results with those of pharmaceutical company representatives, over 60% of physicians mention the brand name drug – a fact that explains the pressure from the pharmaceutical industry on prescribers.

The analysis of data obtained from questionnaires distributed to pharmacists shows that approximately 60% of pharmacists frequently dispense only the reference price drug. However, this fact is contradicted by the result according to which 90% of pharmacists claim that they frequently counsel the patient regarding the alternatives of other brand name drugs. We could conclude that, presently, the decision-making process of dispensing a prescription drug with a certain brand name is shifted toward pharmacies, physicians influencing it less and less.

The OTC Drug and Supplement Market

Beside prescription drugs, we have also analyzed the prescribing/dispensing of OTC (over-the-counter) drugs/supplements. With no limitations from the National Health Insurance House, the prescribing-dispensing chain being direct, the only limitation is the patient's financial potential and the availability of the product in the pharmacy.

Our research emphasizes the fact that 59% of physicians recommend OTC drugs and supplements to complement the treatment administered to a patient. On the other hand, pharmacists declare that in 98% of cases they recommend OTC drugs and supplements to complement the treatment of the given pathology. In accordance with these data, over 75% of physicians and 77% of pharmaceutical representatives consider that the pharmacist recommends OTC drugs and supplements to complement the given pathology.

This number shows us the dimension and potential of the OTC drug/supplement market – there being no price regulations here, but laxity at the level of Direct to Consumer Advertising – it is in the interest of the pharmacy to increase the value of the receipt issued. In fact, several pharmacy chains quantify the number/value of new OTC drug/supplement positions on

the tax receipt – additional to the physician's basic prescription - as a criterion of assessment of their staff.

From an ethical viewpoint, this approach is questionable – and a more consistent regulation is needed at the level of the price of OTC drugs and supplements/mass media advertising etc.

The Physician's Dilemma: Between Compliance with Standard Protocol and Experience. The Off-Label (Unauthorized) Prescription of Drugs

The study found that approximately 93% of physicians firstly consider the standard treatment protocol for a particular diagnosis. In order of importance, we identify clinical observations, experience with a particular molecule, information obtained from recent research and, lastly, meta-analyzes published in significant journals. This result is gladdening, taking into account that it underlines the importance of the therapeutic protocols.

In addition, data analysis revealed that physicians consider the information presented by the pharmaceutical company representatives as rather exact, relatively complex and less balanced by comparison with the competition – this last aspect representing an ethical problem at the level of the industry. Nonetheless, this result should be approached with precaution. The data obtained from pharmaceutical company representatives show that, in order of frequency, the pharmaceutical representative uses the following promotion tools in his relationship with the physician: samples, sponsorships, informal gifts – confirmed by 50% of the surveyed physicians. The role of samples is clearly understood by the pharmaceutical industry, the study emphasizing that 59% of pharmaceutical representatives offer physicians samples. The legislation for prescription/OTC drugs is, of course, different from that for supplements. For prescription drugs, samples may be offered only in the first 5 years since the launch of the product on the market, up to 5 units/physician/year. For supplements, however, there is no regulation in this respect.

We may assume that those who do not offer samples promote prescription or OTC drugs which were launched more than 5 years ago on the Romanian market – because the role of samples is essential in creating the physician's experience with a certain product.

According to the study, pharmaceutical representatives believe that physicians use, in 95% of cases, their experience with a certain drug as a criterion for prescribing a treatment. From the analysis of results obtained for the physicians' questionnaire, we find that approximately 93% of physicians firstly consider the standard treatment protocol for a certain diagnosis. In order of importance, the study identifies clinical observations, experience with a particular molecule (where we can still emphasize the role of samples),

information obtained from recent research and, lastly, meta-analyzes published in significant journals. The importance of samples is probably overestimated by the pharmaceutical industry – experience with a particular molecule being mentioned only as the third aspect in order of importance, when choosing the optimal treatment for a patient.

The Subjectivity of Prescribing and Dispensing Drugs

The 3 batches were surveyed regarding ways of collaboration with the pharmaceutical representative. Physicians and pharmacists were surveyed regarding the ways in which pharmaceutical companies financially supported them by sponsorships. The pharmaceutical representatives were surveyed regarding his practices of collaboration with the two partners. From his point of view, the pharmaceutical representative uses the following tools for promoting products in pharmacies – in order of frequency: commercial offers, sponsorships for the purpose of continuing education, informal gifts. In the pharmacist's opinion, the pharmaceutical representative uses the following ways of collaboration while promoting products, in order of frequency: commercial offers, informal gifts, sponsorships for the purpose of continuing education. On the other hand, physicians have a different vision, considering that the pharmaceutical representative uses in his relationship with the pharmacist, for instance, as a way of promoting the products of pharmaceutical companies, commercial offers and sponsorships for the purpose of continuing medical education, rather than informal gifts. 57% of pharmaceutical representatives claim they often/always make commercial offers (reduction, discounts) to pharmacists. Concerning the data obtained from the batch of pharmacists, over 83% of them claim they receive commercial offers (reduction, discounts) from pharmaceutical company representatives.

These results obtained by comparing answers prove that commercial offers represent the tool used most often by the pharmaceutical industry in its relationship with pharmacies by means of pharmaceutical representatives, a fact which can be explained by the pharmacists' and pharmaceutical companies' wish to have a sustainable business.

Promotion Ethics – what Lies Between the Interest of the Company and the Interest of the Patient's Health?

The pharmaceutical representative's relationship with the prescriber and the pharmacist is complex, being regulated by codes of ethics of the pharmaceutical industry, relying on the ARPIM (Romanian Association of International Medicine Manufacturers) Code. Beside this code, there are various internal codes of ethics, established by each company.

According to our research, the employing company has an official code of ethics for drug promotion; the pharmaceutical representatives' answers are distributed as follows: 91.4% declare they know about the existence of such a code, 4.3% declare the company has no official code of ethics, 4.3% mention they are not aware of an official code of ethics for drug promotion.

The regulations of the ARPIM Code are matched by internal regulations referring to:

- The way to relate to healthcare specialists – most possible aspects being covered by these regulations;
- Criteria for the selection and sponsorship of healthcare professionals, for participation in courses or events;
- Criteria for offering informal gifts (no more than 150 RON/person).

Our conclusion is that the pharmaceutical industry in Romania has self-regulated sufficiently, but slippages can be identified in certain companies.

To outline physicians' and pharmacists' perspective of pharmaceutical company representatives' practices, we have analyzed and compared the answers of the 3 partners. Both physicians and pharmacists consider, to a lesser extent than pharmaceutical representatives, that there is an official company code of ethics for the promotion of its products. The reflection of promotion practices and tools is important in the perception of an ethical type of promotion. For example, when it comes to informal gifts, the data analysis reveals that over 50% of pharmaceutical representatives claim they never give physicians informal gifts. The physicians' perception is different. From the statistical analysis of answers to this question, we identify that, most often (93.5%), physicians make personal financial efforts to support their activities for continuing education and training, which contradicts pharmaceutical representatives' answers, over 45% of them declaring they often/frequently offer sponsorships to physicians for the purpose of continuing medical education. Though only 15% often/always offer sponsorships to physicians, the other 30% admit they occasionally offer such sponsorships.

Moreover, according to the questionnaire dedicated to pharmaceutical representatives, 67% of them consider that physicians cover the costs of activities related to continuing education and training by sponsorships from pharmaceutical companies.

Pharmaceutical Representative – Pharmacist – Physician Relationships, an Important Factor in Dispensing a Drug

The three parties involved in the process of prescribing and dispensing a drug agree on their mutual influence on dispensing a particular drug. 67% of physicians consider that the pharmacist – pharmaceutical representative

relationship is an important criterion, in most cases, for dispensing a prescription drug and 66% of pharmacists claim that the physician's relationship with the pharmaceutical representative is important in prescribing drugs.

A statistically significant difference has been identified depending on the "teaching activity" variable in the batch of physicians. Physicians who also teach consider to a lesser extent than physicians who do not teach that the relationship with the pharmaceutical representative is important in prescribing a certain drug. We corroborate here the data obtained on compliance with protocols and the importance of data obtained from the scientific information flow. It has been observed that physicians who work in academia consider to a lesser extent than physicians who are not that companies employing pharmaceutical representatives have an official code of ethics for drug promotion. In addition, physicians who teach consider to a lesser extent than physicians who do not engage in teaching activities that the pharmaceutical representative uses, in his relationship with the pharmacist, informal gifts and sponsorships for the purpose of continuing education. We may conclude that physicians who also teach value information received from pharmaceutical representatives less, giving more credit to results presented in scientific studies.

Approximately 60% of physicians consider that the relationship between the pharmacist and the physician is important in dispensing a prescription drug; 55% of pharmacists claim that, frequently, the relationship between the pharmacist and the physician is important in this process. Data obtained by this research confirm the studies in the field performed in other countries. Most scholarly studies prove the influence of the pharmaceutical industry on healthcare professionals, but the physician – pharmacist relationship is insufficiently studied and perhaps even undervalued.

4. Perspectives Opened by this Research

This research has addressed a topic which has not been debated so far in Romania. Its conclusions represent, in fact, new research directions, by which future studies may be better guided:

- The physician – pharmacist – pharmaceutical representative relationship,
- The existence of ethical regulations at the level of the pharmaceutical industry; the problems lie in their implementation, because of the fierce competition between various companies, in their pursuit of market share and profit.

Based on the results of our research we can formulate several proposals/recommendations.

1. A first proposal would be the creation of a Central Fund, where sponsorships from the pharmaceutical industry could be collected,

depending on the turnover of each company. The management board of this body would include: physicians, pharmacists and pharmaceutical company representatives. The sum collected in this manner would be equitably distributed to healthcare professionals for activities related to continuing education and training.

2. Another proposal would be to ensure maximum transparency at the level of granting scholarships and informal gifts to healthcare professionals, by proposing legislative projects for the pharmaceutical industry, for the identification, enclosure and sanctioning of deviations in the system. This process is already advanced – from 2015, both healthcare professionals and pharmaceutical companies have been required to declare sponsorships – but the process can be improved.

3. Finding more effective ways of prescription drug reimbursement, to eliminate financial losses from the healthcare system.

4. The proposal of new regulations related to DTC (direct-to-customer) advertising. The national legislation regarding OTCs is according to European legislation, but there are several loopholes for food supplements. In 2015, there was a draft law aiming at a better regulation of this aspect, but in the end the draft did not obtain the final approval, partly because of its deficiencies – it was not especially directed toward supplements/medical devices – the area where the current legislation is the most permissive – from the marketing authorization to the sales process.

5. Giving more attention to the pharmacist – physician relationship – this being an insufficiently studied aspect and, according to the results of our research, an important factor in dispensing prescription drugs.

6. Improving the patient's quality of life by establishing protocols for therapeutic conduct.

5. Conclusions

Our research underlines the ethical dilemma related to aspects related to the prescribing-promoting-dispensing drug process: doctor's prescription is influenced by subjectivity and physicians who also teach value information received from pharmaceutical representatives less, giving more credit to results presented in scientific studies. Pharmacists seem to have more power comparing to doctors, regarding the counseling a certain drug. This paper also presents the limiting factors in the process of drug prescribing and shows that health policies and ethical principles must guide the care for the health of patients.

REFERENCES

- Berwick, D. M., & Hackbarth, A. D. (2012). Eliminating waste in US health care. *Jama*, 307(14): 1513-1516.
- Brody, H. (2010). Medicine's ethical responsibility for health care reform—the top five list. *New England Journal of Medicine*, 362(4): 283-285.
- Brody, H. (2012). From an ethics of rationing to an ethics of waste avoidance. *New England Journal of Medicine*, 366(21): 1949-1951.
- Cassel, C. K., & Guest, J. A. (2012). Choosing wisely: helping physicians and patients make smart decisions about their care. *Jama*, 307(17): 1801-1802.
- Fenton, J.J., Jerant, A.F., Bertakis, K.D., Franks, P. (2012). The cost of satisfaction: a national study of patient satisfaction, health care utilization, expenditures, and mortality. *Archives of internal medicine*, 172(5): 405-411.
- Iorga, M., Sztankovszky, L.Z., C Soponaru, C., Gardikiotis, I. (2015a). Pharmacists' Attitude and Practices about Drug Dispensing in Romania. *FARMACIA*, 63 (4): 601-606.
- Iorga, M., Sztankovszky, L.Z., Soponaru, C., Ioan B. (2015b). Issues in Drug Prescribing Practices in Romania. Opinions of the Pharmaceutical Representatives. *Studia UBB Bioethica*, 2: 11-20.
- Sztankovszky, L.Z., Iorga, M., Astărăstoae, V. (2016a). On ethical practices of pharmaceutical industry stakeholders in Romania under the pressure of latest legislation. *Journal of Applied Ethics and Biolaw*, 1: 43-54.
- Sztankovszky, L.Z., Iorga, M., Astărăstoae, V. (2016b). Pharmaceutical Representatives' Opinion about Pharmacists' Drug Dispensing Practices in Romania and Factors that Influence them. *American Journal of Public Health Research*, 4 (3): 88-92.
- Sztankovszky, L. Z., Iorga, M., Soponaru, C., Astărăstoae, V. (2015a). 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. (2015b). Pharmacists' and Physicians' Perception of Pharmaceutical Representative's Ethical Practices of Drug Promotion in Romania. A Comparative Study. *Postmodern Openings*, 7(1): 189-199.