

Evaluation of Medical Advertising Provided by Pharmaceutical Companies in Printed Drug Advertising Material in Peru

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ABSTRACT

Background: The World Health Organization (WHO) published the "Ethical criteria for medicinal drug promotion" in order to ensure marketing activities to be compatible with the truth search and the integrity that drug marketing and advertising must keep.

Objective: To assess the medical advertising provided by the pharmaceutical companies in printed drug advertising material delivered to physicians working in Peruvian health establishments during 2014 and 2015.

Materials and methods: A cross-sectional study. Drug general data, bibliographical references and registered premises were evaluated, and graphics and descriptive tables were obtained.

Results: 90 printed advertising materials were collected, of which 72 presented bibliographical references. The least registered item was 'contraindications and dose' (55.6%) and in the quality of the references, 21.3% of the premises had no research as basis, being 30.9% of level of evidence 4 and 5, and 33.2% were poorly referenced or did not exist. Of the 566 registered

premises, 14.7% were not supported by any bibliography, and of the remaining premises, we found that 35.9% were controversial and / or deceptive and 51.4% were inaccurate.

Conclusion: The printed drug advertising material delivered to physicians has inaccurate content, use low levels of evidence and grades of recommendation, with poor referencing quality. Furthermore, there are registered premises that are supported by non-existent references or with controversial or deceptive agreements.

Keywords: Propaganda, Marketing of Health Services, Direct-to-Consumer Advertising (MeSH-NLM).

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INTRODUCTION

To prescribe is a scientific, ethic and legal act performed by a physician who has accurate knowledge, has listening and communication abilities, and is able to reflect about the values and attitudes involved in that act (Perez PJ, 2002).

To promote its products, the pharmaceutical industry uses to use printed material; those should show all positive and negative aspects about the drug in question, and must be informative and critically evaluated (Rohra DK *et al.*, 2006; Vilhelmsen A *et al.*, 2016). The promotional literature about drugs must be proportionate relevant information to the health professionals, however, sometimes is inadequate or inexact (Santiago MG *et al.*, 2008). Furthermore, these pharmaceutical promotion activities have a powerful influence over the prescription habits of the physicians, even though can be more subliminal and non-manifest (Jones MI *et al.*, 2001; Khanfar N *et al.*, 2007).

In this situation, the World Health Organization (WHO) published the "Ethical criteria for medicinal drug promotion", which aims to ensure that marketing activities (promotion and publishing) keep relation with the veracity of the provided information (Leonardo Alves T *et al.*, 2018); then has issued pronouncements to strengthen these criteria, since had detected ethically controversial practices (Vacca C *et al.*, 2011).

The pharmaceutical promotion clarity, understood as veracity and responsibility of the divulgation, seeks consumers to be

well informed about benefits and risks related to the prescript drugs (Organización Mundial de la Salud 2006; Viana-Pérez G *et al.*, 2017). Nonetheless, drugs use to have ambiguities in its commercial diffusion, mainly seen in the publishing in the media (Ministério da Saúde 2005; Kornfield R *et al.*, 2015).

In Peru, we don't find studies that evaluate veracity of the premises formulated by the pharmaceutical companies, verifying these to be based in researches. Its approach is very important because the promotion activities influence the prescription behavior of the physicians (Santiago MG *et al.*, 2008). In that way, this study had as objective to assess the medical advertising provided by the pharmaceutical companies in printed drug advertising material delivered to physicians working in Peruvian health establishments of Chiclayo, Peru.

MATERIALS AND METHODS

Study design

The research is exploratory, observational, prospective and cross-sectional, based in the critical valuation of the drug promotional brochures provided in the health establishments of Chiclayo district, Peru.

Population

The study population was formed by all the printed drug advertising material, distributed by the pharmaceutical agents or medical visitors during the period 2014-2015. All sampling frame was used.

Data collection technique

This study has three phases. In the first one, the brochures (advertising) provided to randomly selected physicians were recollected. In the second one, the bibliography search in Lilacs and Pubmed was done, setting appropriate key words or specifically searching the study referenced in the printed advertising material. To the third phase, the advertising was analyzed based in the literature, by two health professionals who previously were trained in critical reading and proficiency in the English language.

Instrument

The questionnaire has three parts, distributed in this way

A) The first section of the questionnaire contains general data such as: code of the evaluation form, laboratory name and the drug data registration (commercial name, generic name, type of drug, active principle, pharmacological group and medical speciality).

➤ The commercial name and generic name were obtained in the advertising.

➤ The active principle was evaluated by International Non-proprietary Name, for which the list of the World Health Organization (WHO) was used (<http://www.who.int/medicines/publications/druginformation/inlists/en/>)

➤ The pharmacological group was classified by therapeutics groups according to the Anatomical, Therapeutic, Chemical classification system (ATC). The ATC is published by the WHO Collaborating Centre to the Methodology of the Pharmaceutical Statistics in Oslo, Noruega, and classifies the drugs according its main therapeutic indication distributing the specialities in 14 main groups (WHO, 2019).

➤ Essential drug or not, according to the list of the Directorate General of Pharmaceutical and Medical Devices (Petitorio Nacional, 2012).

B) Second section, contains data of the extrinsic, external evaluation or evaluation of the register of the advertising contain:

➤ Active principle in International Non-proprietary Name (INN)

➤ Action of the drug or benefits

➤ Pharmaceutical form (presentation type)

➤ Dose (quantity and frequency)

➤ Concentration of the principle active

➤ Adverse Drug Reactions (ADRs) / Secondary effects

➤ Contraindications

C) Third section, contains data about the ethic evaluation such as:

➤ Characteristics of the bibliographical references: number, study type, level of evidence, recommendation grade (Primo J, 2033), reference quality (“Exist, well referenced”, “Exist, bad referenced”, “Not exist”) and if there were of the last 5 years.

➤ Registered premises; classified in accurate (what is indicated in the advertising coincides with the cited study), controversial (based in evidence but this is contradictory) and deceptive (the advertising does not coincide with the cited studies).

Ethic aspects

This study was carried out under the international ethic requirements about the investigation with humans of the Belmont Report, the Good Epidemiological Practice Guide of the ICH, and International Ethical Guidelines for Biomedical Research Involving Human Subjects CI-

OMS, Geneva 2002. The protocol was exempt from review by the “Hospital Nacional Almazor Aguinaga Asenjo” Institutional Review Board.

Statistical data analysis

A database was created in Excel for Windows 2007 and analyzed with the statistical program SPSS version 21. A descriptive analysis was carried out with distribution of frequencies, percentages and measures of central tendency and dispersion of the main quantitative variables. The results were presented in bivariate tables, graphics and bars for better understanding. There were no missing values.

RESULTS

90 printed drug advertising materials were collected, of which 72 presented bibliographic references. The pharmacological groups to which the drugs belonged (according the ATC classification) were mainly: cardiovascular system (n=14), nervous system (n=11) and genitourinary apparatus and sex hormones (n=7). Furthermore, 23 were essential drugs.

In the extrinsic evaluation, the least registered item was “contraindications and dose” with 55.6% (Table 1), in the quality of the references was evidenced that 21.3% of the premises did not have investigation studies as scientific base, being the 30.9% of level of evidence 4 and 5, and in 33.2% the references were bad referenced or inexistent (Table 2).

Table 1: Extrinsic evaluation of the medical advertising provided by the pharmaceutical companies delivered to physicians working in health establishments in the Chiclayo district

Extrinsic (n=72)	%
Active principle	93.1%
Pharmacological action	86.1%
Pharmacological form	76.4%
Dose	55.6%
Concentration	66.7%
Adverse reaction	56.9%
Contraindications	55.6%

Table 2: Quality of bibliographical references registered in the medical advertising provided by the pharmaceutical companies delivered to physicians working in health establishments in the Chiclayo district

Quality of bibliographical references (n=404)	
Study type	
Experimental	54.00%
Analytic	10.60%
Descriptive	12.60%
No Investigations	21.30%
Level of Evidence	
1a/1b/1c	52.20%
2a/2b/2c	10.90%
3a/3b	4.20%
4	2.70%
5	28.20%
Quality of bibliographical references	
Exist, well referenced	56.40%
Exist, bad referenced	37.80%
Not exist	5.40%
Bibliography<5 years	52.20%

Of the 566 registered premises, the 14.7% were not supported by bibliographical references and 35.9% were controversial, deceptive or false (Table 3). In the subjective evaluation of all advertising, regarding the evaluation of what most of the premises refer to, it was found that the 51.4% of the advertising were inexact.

Table 3: Evaluation of the premises registered in the medical advertising provided by the pharmaceutical companies delivered to physicians working in health establishments in the Chiclayo district

Registered premises (n=566)	
Not supported bibliography	14.7%
Agreement	
Accurate	64.1%
Controversial	8.1%
Deceptive	13.1%
False	14.7%

DISCUSSION

This study analyzes the pharmaceutical advertising in Chiclayo, Peru. It was found that 40% of the premises did not have investigation studies as scientific base or were controversial and deceptive. This problem was seen in other studies, even in greater magnitude (Mandoh M *et al.*, 2017). This should mean that pharmaceutical advertising uses to be deceptive in different countries, and does not have solid scientific evidence as base.

Otherwise, only a half of the advertising were of evidence of level 1, similar to reported in studies carried out in Pakistan (Perez PJ, 2002), Australia (Mandoh M *et al.*, 2017) and India (Randhawa GK *et al.*, 2015), which represents an important problem since it could not really provide an adequate and sustained recommendation based on the corresponding medication.

In this study, it was found that the 44% of the pharmaceutical advertising did not declare adverse drug reactions, so that physicians should be alert and check adequately the advertising they receive. Pharmaceutical advertising disrupts ethical principles when publicizes false premises about drugs, eliminates and forgets information about risks and secondary effects, provides material benefits (trips, gifts, and more) to physicians to prescribe them, and uses information about diseases to promote medicine and not promote health (Rodríguez ELR, 2012). Also, must motivate the scientific community and journals to report these ethical faults (Charatan F, 2002) and to not divulge false information in the pharmaceutical advertising (Nath S *et al.*, 2014; Othman N *et al.*, 2009).

Actually, does not exist a mechanism for monitoring the drug promotion campaign of the pharmaceutical industry in Peru, although there is evidence that the problems of rational use of drugs are increasingly widespread; even in developed countries due to the unethical practices of the pharmaceutical industries (Rohra DK *et al.*, 2006; Vina-Pérez G *et al.*, 2017). The problem of the medical advertising is that not only reaches physicians but also general public, which indirectly promotes auto medication, which is a problem reported more and more frequently in Peru (Hermoza-Moquillaza R *et al.*, 2016).

CONCLUSION

The study presents some limitations. For example, only includes establishments of Chiclayo. However, due to the advertising about the drugs uses to be the same, our results can give us a general overview about the reality of the nation. Other limitation was that we did not evaluate how many of the drugs in the advertising had been sometime prescript by

a physician. Future studies in the nation should consider this variable, due to could represent a risk to health.

In conclusion, results of this study suggest medical advertising in Peru need a regulator which follows up this and others activities of the pharmaceutical industry. Physicians must be cautious and critics at the moment of prescription search and investigate about the effectiveness and safety of the affirmations that are reflected in medical advertising.

AUTHOR CONTRIBUTIONS

CDV, LRAV, OEVR participated in the conception and design of the study, VEFR, CCCL, BCM, CJTH participated in the data collection, data analysis, all authors participated in the interpretation. All authors writing the initial draft and redaction. All authors approved the final version and are responsible for the manuscript.

DISCLOSURE

The authors declare to have no compelling interests with this article.

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REFERENCES

1. Perez PJ. La prescripción médica es un acto científico, ético y legal. *Rev Cubana Med Gen Integr.* 2002; 18(2): 114-116.
2. Rohra DK, Gilani AH, Memon IK, Perven G, Khan MT, Zafar H, *et al.* Critical evaluation of the claims made by pharmaceutical companies in drug promotional material in Pakistan. *J Pharm pharm sci.* 2006; 9(1): 50-59.
3. Vilhelmsson A, Davis C, Mulinari S. Pharmaceutical Industry Off-label Promotion and Self-regulation: A Document Analysis of Off-label Promotion Rulings by the United Kingdom Prescription Medicines Code of Practice Authority 2003-2012. *PLoS med.* 2016; 13(1): e1001945.
4. Santiago MG, Bucher HC, Nordmann AJ. Accuracy of drug advertisements in medical journals under new law regulating the marketing of pharmaceutical products in Switzerland. *BMC Med Inform Decis Mak.* 2008; 8: 61.
5. Jones MI, Greenfield SM, Bradley CP. Prescribing new drugs: qualitative study of influences on consultants and general practitioners. *BMJ.* 2001; 323(7309): 378-381.
6. Khanfar N, Loudon D, Sircar-Ramsewak F. FDA direct-to-consumer advertising for prescription drugs: what are consumer preferences and response tendencies? *Health mark q.* 2007; 24(1-2): 77-91.
7. Leonardo Alves T, Poplavska E, Mezinska S, Salmane-Kulikovska I, Andersone L, Mantel-Teeuwisse AK, *et al.* Disease awareness campaigns in printed and online media in Latvia: cross-sectional study on consistency with WHO ethical criteria for medicinal drug promotion and European standards. *BMC public health.* 2018; 18(1): 1322.
8. Vacca C, Vargas C, Canas M, Reveiz L. Drug advertising and promotion: regulations and extent of compliance in five Latin American countries. *Rev Panam Salud Publica.* 2011; 29(2): 76-83.
9. Organización Mundial de la Salud. Uso racional de los medicamentos: progresos realizados en la aplicación de la estrategia farmacéutica de la OMS. Reunión 118 del Consejo Ejecutivo, Informe de la Secretaría (Reporte No.: EB118/6; 2006).

10. Vina-Pérez G, Debesa-García F. La industria farmacéutica y la promoción de los medicamentos. Una reflexión necesaria. *Gaceta Médica Espirituana*. 2017; 19(2): 110-122.
11. Ministério da Saúde. Estudo comparado regulamentação da propaganda de medicamentos 2005.
12. Kornfield R, Alexander GC, Qato DM, Kim Y, Hirsch JD, Emery SL. Trends in exposure to televised prescription drug advertising, 2003-2011. *Am J Prev Med*. 2015; 48(5): 575-579.
13. WHO Collaborating Centre for Drug Statistics Methodology. Guidelines for ATC classification and DDD assignment 2019. Oslo, Norway, 2018.
14. Petitorio Nacional Unico de Medicamentos Esenciales para el Sector Salud Perú 2012.
15. Primo J. Niveles de evidencia y grados de recomendación (I/II). *Enfermedad Inflamatoria Intestinal al Día* 2003; 2(2): 39-42.
16. Mandoh M, Curtain CM. Quality of claims and references found in Australian pharmacy journal advertisements. *Int J Pharm Pract*. 2017; 25(5): 365-370.
17. Randhawa GK, Singh NR, Rai J, Kaur G, Kashyap R. A Critical Analysis of Claims and Their Authenticity in Indian Drug Promotional Advertisements. *Adv med*. 2015; 2015: 469147.
18. Rodriguez ELR. Bioética, medicamentos, conflicto de intereses y control de calidad. *Derecho PUCP*. 2012; 69: 245-257.
19. Charatan F. Doctor sues company over unethical marketing. *BMJ (Clinical research ed)*. 2002; 324(7348): 1234.
20. Nath S, Bhowmick S, Dutta T, Chowrasia VR, Bhattacharya S, Chatterjee RN, *et al*. A study of promotional advertisements of drugs in a medical journal: an ethics perspective. *Indian J Med Ethics*. 2014; 11(4): 237-241.
21. Othman N, Vitry A, Roughead EE. Quality of pharmaceutical advertisements in medical journals: a systematic review. *PloS one*. 2009; 4(7): e6350.
22. Hermoza-Moquillaza R, Loza-Munarriz C, Rodríguez-Hurtado D, Arellano-Sacramento C, Hermoza-Moquillaza V. Automedicación en un distrito de Lima Metropolitana, Perú. *Revista médica herediana*. 2016; 27(1): 15-21.