Research Article

Quality Assessment of Pharmaceutical Advertisements Based on WHO Guideline in Hodeidah City, Yemen

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ABSTRACT

The aim of this study was to analyze and assess the accuracy and reliability of the pharmaceutical drug advertisements in Hodeidah city. It was also to identify the adherence of the pharmaceutical companies to apply the World Health Organization (WHO) - ethical criteria for medicinal drug advertisements. 100 Pharmaceutical Advertisements (PA_S) were collected from licensed pharmacies, clinics and hospitals in Hodeidah city, Yemen and estimated based on WHO requirements and scientific literatures. On the other hand, the PA information of the developed and developing countries was recorded and compared. The results of the international nonproprietary name showed that the generic name was (100%). The pharmacological information was estimated and the results showed that: (18 %) was the pharmacokinetic; (39 %) the mechanism of action; (12 %) the drug – drug interaction and (3 %) the drug – food interaction. In addition, the clinical information that was recorded approved therapeutic use (99 % of indication, 66 % of dose in a day, 39 % of time duration), 85 % of dosage regimen, 35 % of contraindication, 36 % of adverse effects, 31 % of precaution. Using of drugs in pregnancy and lactation and overdose management were found to be 16 %, 13 % and 8 % respectively. In addition to that, treatment success in 33 %, life style and necessary behavioral changes were noted in 1 % and reference to scientific literature was recorded in 39 %. The economical information results were 96% of names and addresses of manufacturer or distributor, 13 % of available competing treatment and 0 % of price of drug product. Finally, the maximum values were observed in developed countries and the minimum values were observed in developing but in general, the developed, developing and unknown countries' name in this study did not meet the acceptance ethical criteria for WHO guideline and scientific literature. Therefore, the pharmaceutical companies must comply the WHO requirements because the poor quality of PAs could contribute with failure of treatment protocol use.

Keywords: Pharmaceutical Advertisements, WHO, Developing Countries, Quality, Hodiedah, Yemen.

INTRODUCTION

The increasing globalization of the pharmaceutical industry is a well-recognized phenomenon in parallel to the development of pharmaceutical advertisements (PA_S) for these industries with the increased use of mass media advertising for prescription medicines [1,2].

PA_S are to support and encourage the improvement of pharmaceutical health care. In addition, PA_S to the general public should help people to make rational decisions on the use of drugs determined to be legally available without a prescription[3]. On the other hand, the PA is to convince physicians to prescribe the manufacturer's product[4] and the main sources of medicines information to help them ensure safety, effectiveness, security of a wide range of products and to determine the optimal use of medicines[5]. PA_S must have the accuracy and reliability and science - based information for this purpose [6, 7].

Despite the availability of regulations and controls of drug promotion worldwide, information on medicines provided in journal advertising has been criticized in several studies for being of poor quality[8]. Therefore, this study aimed to evaluate the accuracy, rationality and quality of PAs and presentation of risk results in Hodeidah city, Yemen. Also a comparative study has been conducted on the quality of PAs of developed and developing countries to comply ethical criteria for medicinal drug promotion of World Health Organization (WHO) guideline and scientific literature[9, 3].

MATERIALS AND METHODS

Hundred samples of PA_S for different pharmaceutical companies were collected randomly from licensed pharmacies, clinics and hospitals in Hodeidah city. However, the samples were collected at various levels of specialists, such as a pediatric, cardiologist, gastrointestinal, infection disease, endocrinologist, dermatologist, gynecologist and neurologist. These samples were evaluated by using WHO - ethical criteria for medicinal drug promotion namely name(s) of the active ingredient(s) using either international nonproprietary name (INN); the approved generic name of the medicine; content of active ingredient(s) per dosage regimen; pharmacological information (pharmacokinetic, mechanism of action, drug – drug interaction and drug – food interaction); clinical information (side effects, precautions, contraindications, overdose management, use in pregnancy, use in

lactation, approved therapeutic use namely dose in a day, treatment duration), economical information (name and address of manufacturer or distributor, available competing treatment and price of drug product), reference to scientific literature as appropriate and the life style and necessary behavioral changes based on scientific literature.[3,9]

RESULTS AND DISCUSSION

Hundred samples of different brochures of PA_S were collected from licensed pharmacies, clinics and hospitals. The basic information of the collected PAs was shown in Table 1 and 2. The APs are produced by different countries viz 22 developed countries, 57 developing countries and 21 unknown countries' name as shown in table 1. On the other hand, the PAs were classified according to pharmacological classes (Table 2).

The quality assessment of 100 PA_S was shown in figure 1, the maximum values were observed in NNI (100 %) and indication (99 %). The minimum values were observed in life style and necessary behavioral changes (1 %) and price of drug product (0 %).

The results of PAs quality of developed, developing and unknown countries' name were given in table 3 and showed that the PAs of the developed countries comply with WHO - ethical criteria for medicinal drug promotion better than developing and unknown countries' name in most criteria.

Table 1: Basic information of PA_S

Countries	No
Developing countries	
• India	12
• Egypt	36
• Jordan	4
• Yemen	2
• Emirate	1
• Turkey	1
• Thailand	1
Developed countries	
• Italy	3
• France	1
• England	1
• Germany	4
• Switzerland	6
• Korea	1
• Finland	1
• Malaysia	1
• Spain	1
• Belgium	1
• Australia	2
Unknown countries' name *	21
Total	100

*: 21 unknown countries' name that 4 APs with unknown manufacturers and distributers, 14 APs with unknown of manufactures only and 3 APs with unknown distributers.

Table 2: Pharmacological information of PA_S

No	Pharmacological classes	Ratio
1	Anti-acne	4 %
3	Anti-allergy	3 %
4	Antibiotic	24 %
5	Anti-bleeding	1 %
6	Anti-cancer	2 %
7	Anti-cough	1 %
8	Anti-diabetic	2 %
9	Anti-emetic	2 %
10	Anti-fungal	2 %
11	Anti – infertility	2 %
12	Anti-hypertensive	4 %
13	Anti-hyperlipidemia	1 %
14	Anti-parasite	3 %
15	Anti – Parkinson	1 %
16	Anti-peptic ulcer	4 %
17	Anti – Pyretic	1 %
18	Anti-psychotic	1 %
19	Anti – rheumatic	1 %
20	Anti-spasmodic	3 %
21	Anti – tuberculosis	1 %
22	Antiviral	2 %
23	Cerebral Metabolism	1 %
24	Hepatoprotective	2 %
25	Hormones	3 %
26	Immunostimulant	2 %
27	Multi-vitamin	13 %
28	Memory disorder	1 %
29	Non Steroid Anti - inflammations (NSAIs)	11 %
30	Stone Dissolved	2 %
Total		100 %

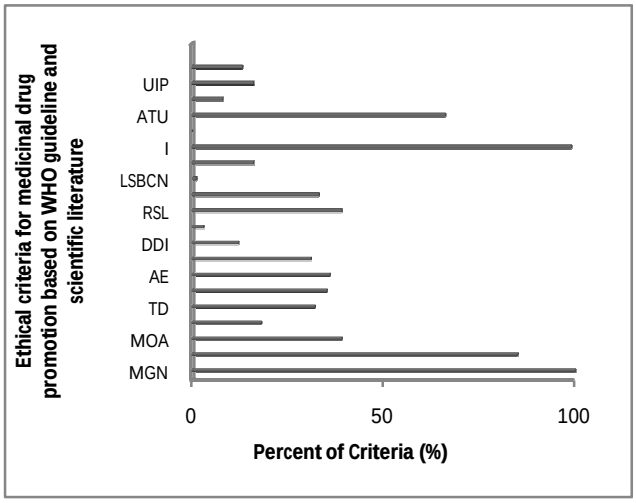

Figure 1: Results of quality assessment of PA_S in Hodeidah city, Yemen by using WHO guideline;

MGN : mentioned the generic name (100 %), DR : dosage regimen (77 %), PK: Pharmacokinetic (18 %), MOA : mechanism of action (72 %),I: indication (99 %), TD: treatment duration (32 %), CI : contraindication (35%), AE: adverse effects (36 %), PR: precaution (31%), DDI : Drug – Drug Interaction (12 %), DFI : Drug – Food Interaction (3%), RSL : reference to scientific literature (39 %), TS: treatment success (33 %), DID: Dose in Day (66 %), life style and behavioral changes necessary (1 %), ACT : Available Competing Treatment (13 %) and P: price of drug product (0 %). UIP: Using in Pregnancy (16 %), UIL: Using in Lactation (13 %), LSNBC : Life Style and Necessary Behavioral Changes (1 %). ODM: Overdose Management (8%), NAMD: Name and Address of

Manufacturer or Distributor, ACT: Available Competing Treatment (13 %) and P: Price of Drug Product (0 %).

But in general, the quality available in INN was only (100 % in all countries) while low quality in pharmacological information (50 % of mechanism of action was recorded in the developed countries and 0 % of drug – food interaction was recorded in the developing and unknown countries' name), clinical information (100 % of indication was mentioned in the developed and unknown countries' name and 4.76% of using of drugs during lactation was observed in the unknown), economical information (100 % of name of manufacture or distributor were shown in the developed and developing countries and 0 % of price of drug product was shown in all countries).

1 % of life style and necessary behavioral changes was recorded in the developed countries and 0 % in the developing and unknown countries' name. 50 % of reference to scientific literature was mentioned in the developed countries and 28.27 % in the unknown countries' name. In brief, the maximum values were observed in the developed countries and the minimum values were observed in the developing and unknown countries' name. In conclusion, the developed, developing and unknown countries' name in this study did not meet the acceptance ethical criteria for WHO guideline and scientific literature (Table 3).

Table 3: Results of PA_S quality

No of Pas	Developed countries n = 22	Developing countries n = 57	Unknown countries' name n = 21
INN	100	100	100
Pharmacological Information (%)			
• Pharmacokinetic	18.18	17.54	14.28
• Mechanism of action	50.00	43.85	19.04
• Drug – Drug Interaction	27.27	08.77	04.76
• Drug – Food Interaction	13.63	00.00	00.00
Clinical Information (%)			
• Dosage regimn	90.47	87.71	71.42
• Indication	100	98.24	100
• Approved therapeutic use			
- Dose in day	72.72	68.42	52.38
- Time duration	45.45	28.07	28.57
• Adverse effect	72.72	24.56	33.33
• Precaution	54.54	24.56	23.80
• Contra - indication	72.72	22.80	28.57
• Overdose management	13.63	07.01	04.76
• Use in pregnancy	22.72	15	09.52
• Use in lactation	18.18	13.38	04.76
	01.00	00.00	00.00
Treatment Success (%)	54.54	24.56	28.57
Life style (%)	01.00	00.00	00.00
Economical Information (%)			
• Price of pharmaceutical product	00.00	00.00	00.00
• Available competing treatment	27.27	10.52	14.28
• Name of manufacture or distributor	100	100	95.00
Reference to Scientific Literature (%)	50.00	36.84	28.57

In comparison with previous studies, there are substandard APs within the analysis of written pharmaceutical advertisement in Dubai & Sharja, 98.5% mentioning condition for which targeted drug was used, condition prevalence rate in 11% of advertisements, mechanism of action was mentioned in 47 %, incomplete information in 63%, clear misleading information in 5%, success estimates of treatment in 50% and reliability was noted in 3% of advertisements[9].

Previous studies in India revealed that the poor-quality PAs are highly distributed and circulating intensively in the pharmacies, clinics and hospitals. However, rationality of promotional drug literature using WHO guideline was evaluated and majority (92%) brochures claimed about the efficacy of product, and a few about safety (37.8%). Out of 1003 references given in support of various claims, 84.4% were from journals and only 28.5% were validly presented researches. Brochures presenting irrelevant pictures were 41.3%, whereas brief prescription information (BPI) of the promoted drug was given only by 8.8% brochures[10]. Other study in India was recorded, safe prescribing information on major adverse drug reactions, contraindications and warnings was provided, only 19 advertisements of 292 drug claims, and only 80 (27%)

were supported with reference (s)[11]. Also, drug advertisements published in Indian medical journals were evaluated by Jaykaran et al and generic name was mentioned in 90% advertisements, indications were mentioned in 84% advertisements. Dose, precautions and contraindications were mentioned in 24%, 17%, and 16% advertisements respectively. Adverse effects and postal address of pharmaceutical company were mentioned in 19% and 74% advertisements respectively. Price was mentioned in only 5% advertisements. Only 28% claims were supported by references. Most common references were journal articles (75%). Drug advertisements published in Indian Medical Journals were poor in reporting various parameters according to WHO criteria[12].

In Australia, Malaysia and USA, quality of claims, references and the presentation of risk results in medical journal advertising were compared. Less than one-third of the claims were unambiguous (Australia, 30%, Malaysia 17%, US, 23%). The majority of claims were vague suggesting poor quality of claims in journal advertising in these three countries[5]. Also, pharmaceutical advertisement claims in Australian medical publications was evaluated by Tim et al and the results of 1504 claims, 855 could be substantiated quantitatively. Of these, 45 % were supported by compelling evidence [13].

Evaluation of PAs in Switzerland revealed that accuracy of drug advertisements in medical journals under new law regulating the marketing of pharmaceutical products was substandard, 53% of all assessed pharmaceutical claims published in major medical journals were not supported by the cited referenced studies or based on potentially biased study information [14].

On the other hand, in Spain, accuracy of pharmaceutical advertisements in medical journals was not supported by the reference[15]. In addition, adequacy of drug advertisements distributed to prescribers in Southern Brazil was substandard. However, the analysis demonstrated that most advertisements fail to comply with either the Brazilian legislation on medicinal products and/or the WHO ethical criteria for medicinal drug promotion[16].

Drug company advertising in medical journals about the health-economic advantages of their products for 2000-2006 versus 1990-1999 was described in USA by Palmer et al and their study revealed that the use of supporting references in the body of advertisements has not improved over time[17]. Also, industry guidelines, laws and regulations were ignored. Quality of drug advertising in medical journals was recorded by Lankinen et al. They concluded that referenced marketing claims may appear more scientific, but the use of references does not guarantee the quality of the claims.[18]

A previous study and our research concluded that reasons of low quality of PA_S may include absent laws and regulations ignored. Therefore, control programmes should establish efficient systems to estimate the requirements of PA efficacy especially in developing countries where the problems of quality failure predominantly occur due to lacking of effective drug regulatory agencies. PA_S should be subjected to more strict regulations before being published and physicians should be cautious about the reliability of information in all drug advertisements and should follow principles of evidence-based medicine in assessing the validity of information on targeted drugs[9]. PA_S quality estimation system would encourage the manufacturers to improve their advertisements and help to identify good or poor-quality pharmaceuticals treatment for physicians and assure the use of drug product for consumers.

CONCLUSION

In conclusion, this study showed poor quality of PA_S available in Hodiedah city, Yemen and this could be attributed to the absence of efficient regulatory systems. Poor quality of PA_S may affect the efforts to control disease and could contribute to failure of treatment protocol use while providing high quality PA_S will significantly reduce error related to drug use and has greater efficacy and safety. Finally, to improve this situation it thus seems necessary to develop more effective systems to estimate quality of information provided to prescribers by the drug advertisers.

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