Content audit of drug advertisements in Pakistan

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Abstract

A sample of 120 drug advertisements was drawn by non-probability convenience sampling from among the stalls of 50 pharmaceutical companies participating in an exhibition in Karachi, Pakistan. 23 belonging to the NSAID drug group were selected and evaluated on whether they met guidelines for ethical advertisements as laid down in the Drugs Act, 1976. Only 5 out of the 23 advertisements met at least 14 out of 16 criteria for ethical advertisements as given in the Drugs Act, 1976.

Introduction

There is evidence that irrational pharmacotherapy is increasingly encountered in developing countries due to unethical pharmaceutical promotion (1, 2). Anecdotal evidence suggests that information provided to physicians in drug advertisements is inaccurate. It is important to study the contents of drug advertisements as they influence healthcare providers' prescribing behaviour (3)

Ethical criteria and legal framework for drug promotion

In Pakistan, the Drugs Act, 1976 (4), contains "criteria for medicinal drug promotion" in advertisements The Act requires drug advertisements to meet 16 criteria comprising categories of information and the manner in which this information is presented.

The advertisements must mention the following: [1] the approved generic name(s) of the active ingredient(s); [2] the content of active ingredient(s) per dosage form or regimen; [3] the generic name(s) of other ingredient(s) known to cause problem(s); [4] approved therapeutic uses; [5] dosage form or regimen; [6] side-effects and major adverse drug reactions; [7] precautions, contraindications and warnings; [8] major interactions and [9] references where appropriate to authenticate claims. Further, they must contain [10] the retail price of the drug; [11] name and address of manufacturer or distributor; and [12] a statement that complete information would be provided on request.

Finally, the advertisements must [13] be legible; [14] avoid superlatives such as "the most potent" or "effective in all cases"; [15] avoid exaggerated claims and [16] make no direct or indirect comparison with any other drug.

However, drug advertisements do not always meet all these criteria, and there is no mechanism to enforce the law in this matter.

Methods

A sample of 120 promotional advertisements was drawn by non probability convenience sampling from among the stalls of 50 pharmaceutical companies that participated in an exhibition held in December 2008 in Karachi, Pakistan. Out of these 120 samples, 23 advertisements belonged to the NSAID drug group, and these were selected for analysis vis a vis the Drugs Act, 1976. NSAIDs were selected because they remain the most commonly prescribed over-the-counter drugs.

The advertisements were separated into two groups according to whether they were from local or from multinational companies (MNC). Nine of the 23 advertisements were of MNC drugs. All the advertisements were graded according to the number of criteria they fulfilled of the Drugs Act, 1976 (Table). The grading system was as follows: Grade A was awarded when at least 14 out of 16 criteria were fulfilled in the advertisements. Grade B was awarded when 12-13 criteria were met. Grade C was awarded when 10-11 criteria were met. Grade D was awarded when 9 or fewer criteria mentioned in the Drugs Act, 1976, were met.

Results

Summary

The writing in 19 advertisements was legible [i]; in 4 advertisements, the writing was too small to read easily. All 23 advertisements mentioned the approved generic name of the active ingredient [ii]. 16 of 23 mentioned the quantity of the active ingredient per dosage form or regimen [iii]. Only 1 of 23 advertisements mentioned the generic name of other ingredients known to cause problems [iv]. 20 of 23 advertisements mentioned the approved therapeutic uses [v]. 15 of 23 mentioned the dosage form or regimen [vi]. 11 of 23 advertisements mentioned the side-effects and major adverse drug reactions [vii]; precautions, contraindications and warnings [viii]; and major drug interactions [ix]. Information on the drug price was missing in all but three of 23 advertisements [x].

Only 10 of 23 advertisements refrained from using superlatives [xi], only 7 of 23 refrained from making comparisons with other drugs [xii], and 14 of 23 contained no exaggerated claims [xiii]. 19 of 23 advertisements provided references where appropriate [xiv]. 14 of 23 stated that complete information would be provided on request [xv]. 22 of 23 mentioned the name and address of the manufacturer or distributor [xvi].

Grades

Only 5 of 23 pharmaceutical advertisements met at least 14 of 15 criteria and fit in Grade A. 4 of these ads were from MNCs and 1 from a local company.

4 advertisements met 12 or 13 of the criteria and fit in Grade B. 1 of these ads was from an MNC and the other 3 were from local companies.

5 advertisements met 10 or 11 of the criteria and fit in Grade C. Of these, 1 was from an MNC and the other 4 from local companies.

9 of 23 advertisements fulfilled 9 or less out of the maximum 16 criteria of the Drugs Act, 1976, and fit in Grade D. 3 of these were from MNCs and 6 were from local companies.

Significant discrepancies were found in the advertisement contents. They did not contain essential information such as dosage, side-effects, precautions, scientific evidence and drug interactions. They did contain various inaccurate, misleading and unethical claims.

Examples

9 of 23 ads made exaggerated or unsubstantiated claims such as: *"As safe as placebo", "a record of worldwide experiences", rarely associated with side effects","drug of choice", "the most economical in Pakistan," and "is about 20 times more effective than aspirin and ibuprofen."* Such unscientific, false claims are known to influence the prescribing behaviour of physicians.

13 of 23 advertisements employed unjustified superlatives, specifically when comparing their drug with that of their competitors. To quote an example: *"Flubiprofen is the most potent inhibitor of PG synthesis than ibuprofen, indomethacin and aspirin".*

The most commonly noted violation - found in 16 out of 23 ads -- was comparing the company's drug with others. For example:*"The pain control was superior with NSAID as compared to diclofenac following third molar extraction."*

8 ads made exaggerated and unsubstantiated claims, and used unjustified superlatives while also comparing their drug with their competitors.

Discussion

This is the first study in Pakistan auditing the contents of promotional advertisements by pharmaceuticals to see if they conform to the framework laid down in the Drugs Act, 1976. A previous study (2) has looked at claims made by pharmaceutical companies in Pakistan but not specifically in relation to the law.

Studies have shown that drug advertisements are regarded by physicians in Pakistan as a means to keep up to date on the company's products, and they influence prescribing behaviour (5). Studies have also pointed to an unhealthy nexus between physicians and manufacturers here (2).

Currently there are 441 pharmaceutical manufacturers registered in Pakistan. Of these, 411 are local and 30 are MNCs (6). Our study suggests that MNCs are better in following the codes of advertisements as compared to local manufacturers. It may be that MNCs are required to follow the practices of their headquarters in western Europe and North America, where monitoring is strict and penalties for infraction are substantial. Local manufacturers operate in an environment which for all purposes is unregulated, and they exploit this deficiency in the state monitoring mechanism.

The majority of the advertisements that we analysed were found to be poorly organised and filled with irrelevant and misleading claims. The term "safety" was used in a number of places without supporting scientific evidence. Essential information was not presented, was inaccurate, or was printed in small, difficult-to-read fonts.

Information on the price of the medicine was left out in most of the advertisements in this study. In a country like Pakistan, where there is no health insurance and a substantial proportion of the population lives below the poverty line, the onus is on physicians to make choices for patients under their care, and highlighting the price of a drug would help them in ethical decision making.

Conclusion

Pharmaceutical advertisements subtly influence the prescribing behaviour of health providers and therefore affect the end user of these drugs, the patient. Prescription of irrational and/or harmful drugs is both unethical and dangerous.

We call for drug advertisements that are accurate, honest and informative; that present risks and benefits in an unbiased manner and are capable of withstanding scientific scrutiny. Advertisements should not contain misleading, unverifiable claims with the intention of subliminally conditioning the physicians' prescribing behaviour. Claims should be based on scientific evidence, and references should be provided for this scientific evidence supporting claims so that physicians can retrieve the publications for their independent evaluation.

The competent authorities must actively monitor advertisements to ensure that they comply with the law, and impose penalties in cases of non-compliance. It is also important to teach our physicians how to analyse the contents of advertisements to enable them to meet their moral and professional obligations to their patients.

Given the sampling method and the small sample in this study, the findings cannot be generalised. However, they can be used towards more systematic work in this subject in Pakistan and other countries in this region.

References

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Table: Promotional material audited as per the criteria of the Drugs Act, 1976

Drug information		Ethical criteria for drug advertisements																
Brand name	***Generic name***	**i**	**ii**	**iii**	**iv**	**v**	**vi**	**vii**	**viii**	**ix**	**x**	**xi**	**xii**	**xiii**	**xiv**	**xv**	**xvi**	**Grade***
Anex	Naproxen sodium	✓	✓	✓	×	✓	✓	✓	✓	✓	✓	✓	×	✓	✓	✓	✓	A
Profenid	Ketoprofen	✓	✓	✓	×	✓	✓	✓	✓	✓	×	✓	×	✓	✓	✓	✓	A
Feldene	Piroxicam	×	✓	✓	×	✓	✓	✓	✓	✓	×	✓	✓	✓	✓	✓	✓	A
Febrol	paracetamol	✓	✓	✓	✓	✓	✓	✓	✓	✓	×	✓	✓	✓	✓	✓	✓	A
Ponstan	mefenamic acid	✓	✓	✓	×	✓	✓	✓	✓	✓	×	✓	✓	✓	✓	✓	✓	A
Flubi	Flurbiprofen	×	✓	✓	×	✓	✓	✓	✓	✓	×	✓	×	✓	×	✓	✓	B
Ansaid	Flurbiprofen	✓	✓	✓	×	✓	✓	✓	✓	✓	×	×	×	✓	✓	✓	✓	B
Voren	Diclofenac sodium	✓	✓	✓	×	✓	✓	×	×	×	×	✓	✓	✓	✓	✓	✓	B
Tormax	Naproxen sodium	✓	✓	×	×	✓	✓	✓	✓	✓	×	×	✓	✓	✓	×	✓	B
Unix	Nimesulide	×	✓	✓	×	✓	✓	✓	✓	✓	×	×	×	×	✓	×	✓	C
Panslay	Diclofenac sodium	✓	✓	×	×	✓	✓	×	×	×	×	✓	✓	✓	✓	✓	×	C
Brufen	Ibuprofen	✓	✓	✓	×	✓	✓	×	×	×	✓	✓	×	✓	✓	✓	✓	C
Dorsiflex	Celecoxib	✓	✓	✓	×	✓	✓	✓	✓	✓	×	×	×	×	✓	×	✓	C
Cyclodex	Piroxicam	×	✓	✓	×	✓	✓	✓	✓	✓	×	×	×	×	✓	×	✓	C
Airtal	Aceclofenac	✓	✓	×	×	×	×	×	×	×	×	×	×	✓	✓	×	✓	D
Neurofenac	Diclofenac Sodium	✓	✓	×	×	✓	×	×	×	×	×	×	×	×	×	✓	✓	D
Naplur	Flurbiprofen	✓	✓	✓	×	✓	×	×	×	×	×	×	×	×	✓	×	✓	D
Modact-IR	Nimesulide	✓	✓	×	×	×	×	×	×	×	×	×	×	✓	×	✓	✓	D
Oragesic	Flurbiprofen	✓	✓	✓	×	✓	✓	×	×	×	×	×	×	✓	✓	×	✓	D
Froben	Flurbiprofen	✓	✓	✓	×	✓	×	×	×	×	✓	×	×	×	✓	✓	✓	D
Synalgo	Flurbiprofen	✓	✓	×	×	×	×	×	×	×	×	×	×	×	✓	×	✓	D
Altoron	Diclofenac Sodium	✓	✓	✓	×	✓	×	×	×	×	×	✓	✓	×	×	×	✓	D
Pcam	Piroxicam	✓	✓	×	×	✓	×	×	×	×	×	×	×	×	✓	✓	✓	D

Criteria

i. Legibility;
ii. Approved generic name(s) of the active ingredient(s);
iii. Content of active ingredient(s) per dosage form or regimen;
iv. Generic name(s) of other ingredient(s) known to cause problem(s);
v. Approved therapeutic uses;
vi. Dosage form or regimen;
vii. Side-effects and major adverse drug reactions;
viii. Precautions, contraindications and warnings;
ix. Major interactions;
x. Retail price of the drug;
xi. Absolute characters, such as "the most potent", "the most rapid", "the most "effective in all cases" or superlatives shall be avoided;
xii. No direct or indirect comparison in any way with any other drug;
xiii. Exaggerated claims should be avoided;
xiv. References should be provided where appropriate to authenticate claims;
xv. Provision of full information on request should be highlighted;
xvi. Name and address of manufacturer or distributor.

* ***Grading:*** *A: 14-16 criteria met; B: 12-13 criteria met; C: 10-11 criteria met; D: 9 or fewer criteria met.*