Pharmaceutical Advertisements in Indian Scientific Journals: Analysis of Completeness of Information Content

Dr. Jignesh K Ved1*, Dr. Sagar S Jagtiani1, Dr. Kunal A Chitnis1

1Department of Pharmacology; Topiwala National Medical College and B.Y.L.Nair Charitable Hospital; Mumbai-Central; Mumbai; 400008; Maharashtra; India.

Abstract:

Purpose: In India, pharmaceutical advertising is governed by ‘The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954’, and ‘The Drugs and Cosmetics Rules, 1945’. These acts do not specify the ‘minimum essential information requirements’ for an advertisement, keeping this area ill-defined. The ‘Organization of Pharmaceutical Producers of India (OPPI)’, in its ‘Code of Pharmaceutical Marketing Practices’, provides a guideline for the information requirements in advertisements. Our study is intended to analyze the ‘completeness of information content’, in pharmaceutical advertisements, published in 2009-10 in Indian Scientific journals, in the context of OPPI code.

Method: Indian Scientific Journals (2009-10 issues) were surveyed for pharmaceutical advertisements. Advertisements were classified as ‘Full’ or ‘Reminder’ advertisements and were separately analyzed for the presence of information on ‘Brand name’; ‘Active ingredient(s)’; ‘Marketer’s Name and Address’; ‘Date of Production of advertisement’; ‘Abbreviated Prescribing Information (only for Full advertisements)’ and ‘Overall completeness’. Data was expressed as absolute numbers and percentage.

Results: Full advertisements (n=34) demonstrated 41.2% of ‘Overall completeness’. ‘Date’ was missing in 52.9%, while ‘Marketer’s Name and Address’ in 17.6% of advertisements. ‘Active ingredient’ was mentioned in all, while ‘Abbreviated Prescribing Information’ was complete in 97.1% of Full advertisements.

Reminder advertisements (n=134) demonstrated 10.4% of ‘Overall completeness’. ‘Date’ was missing in 88.1%, ‘Marketer’s Name and Address’ in 29.1% and ‘Active ingredient’ in 8.2% of Reminder advertisements.

Conclusion: Low percentage of completeness, as observed in our study, indicates a lack of adherence to OPPI code and need for mandatory regulations, to ensure information completeness in pharmaceutical advertisements.

Keywords: Pharmaceutical Advertisements; Information content; OPPI Code of Pharmaceutical Marketing Practices; The Drugs and Magic Remedies act; The Drugs and Cosmetics rules.

Introduction:

Pharmaceutical product advertising, in India, is regulated mainly by ‘The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954’ [1] and by ‘The Drugs and Cosmetics Rules, 1945’ [2]. These acts provide for the consistency of the advertisements with the approved prescribing information, prohibition of certain types of advertisements, and penalties against any instance of breach of these mandatory requirements [1,2,3].

These acts, however, do not provide for the requirement of ‘minimum essential information content’, to be present in the pharmaceutical advertisements. Thus, this minimum requirement of information for a pharmaceutical advertisement, which is an important consideration, remains ill-defined.

The ‘Organization of Pharmaceutical Producers of India (OPPI)’, a non-government scientific organization, is an active Indian member of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) [4]. The OPPI provides guidelines for pharmaceutical marketing, which are based on the ‘IFPMA Code of Pharmaceutical Marketing Practices’. They are known as the ‘OPPI Code of Pharmaceutical Marketing Practices’.
Although not mandatory, the code provides good guiding principles, which may be followed for better marketing of the pharmaceutical products.

The requirements of information content in pharmaceutical advertising, as provided in ‘Section 5’ of the OPPI code, are as follows [4]:

“5.1: All printed promotional materials, other than those covered in 5.2 below, must be legible and include:

- The ‘name’ of the product (normally the brand name);
- The ‘active ingredients’, using approved names where they exist;
- The ‘name and address’ of the pharmaceutical company or its agent responsible for marketing the product;
- The ‘date of production’ of the advertisement;
- The ‘abbreviated prescribing information’ which should include an approved indication or indications for use together with the dosage and method of use; and a succinct statement of the contraindications, precautions and side effects.

5.2: Reminder Advertisements:
A “reminder” advertisement is defined as a short advertisement containing no more than the name of the product and a simple statement of indications to designate the therapeutic category of the product. For “reminder” advertisements, “abbreviated prescribing information” referred to in 5.1 above may be omitted.”

For an advertisement, the utility of information contents described by the OPPI code may be:

- Product name is the Brand name that identifies the formulation of a specific manufacturer.
- Active ingredient(s) is the active principle(s) or the generic drug(s) present in the formulation, which directs the therapeutic action of the prescriber.
- Name and Address of the marketer is the contact information, necessary for the feedback for the queries regarding the information; requisition of detailed drug-related information; or notifying occurrence of adverse event with the drug-use, particularly for new drugs.
- Date of Production of the advertisement is important, as the drug-related information may be subjected to change with further findings.
- Abbreviated prescribing information is required particularly for Full advertisements, with brief drug-related information in terms of the approved Indication(s), Dosage and method of use, the known Contra-indications, Precautions and Side effects. This is the basic essential information required for any drug-therapy.

The objective of our study is to analyze the ‘completeness of information content’, in pharmaceutical advertisements published in 2009-10 in Indian Scientific journals, in the context of OPPI code.

Materials and Methods:

Pharmaceutical advertisements, published in the last two years (2009-10 issues), observed from the Indian Scientific journals of various medical and surgical specialties were analyzed.

Advertisements were classified as:

a) Full Advertisements  b) Reminder Advertisements.

‘Full’ and ‘Reminder’ advertisements’ were analyzed separately for the presence or absence of the following information:

- Name of the product (Brand name)
- Active ingredient(s)
- Name and Address of the marketer
- Date of Production of the advertisement
- Abbreviated Prescribing Information (analyzed only for the Full advertisements), including information on Indication(s) for use; Dosage and method of use; Contra-indications; Precautions and Side effects
Overall completeness: It was defined by the presence of all the information parameters. ‘Overall completeness’ was analyzed separately for Full and Reminder advertisements.

Findings of our observational study were expressed as absolute numbers as well as percentage.

**Results and Discussion:**

A total of 10 different journals, including 26 volumes and 2 supplements, were surveyed for pharmaceutical advertisements. 323 advertisements were obtained and screened for duplication. After screening, 168 advertisements, including 34 Full advertisements and 134 Reminder advertisements, were selected for analysis.

The observations of the information content analysis, for the Full and Reminder advertisements, are presented, in the form of absolute number and percentage, in Table 1.

<table>
<thead>
<tr>
<th>Advertisement</th>
<th>Product Name</th>
<th>Active Ingredient</th>
<th>Name and Address of Marketer</th>
<th>Date of Production of Advertisement</th>
<th>Abbreviated Prescribing Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full (n=34)</td>
<td>34 (100%)</td>
<td>34 (100%)</td>
<td>28 (82.4%)</td>
<td>16 (47.1%)</td>
<td>33 (97.1%)</td>
</tr>
<tr>
<td>Reminder (n=134)</td>
<td>134 (100%)</td>
<td>123 (91.8%)</td>
<td>95 (70.9%)</td>
<td>16 (11.9%)</td>
<td>-</td>
</tr>
</tbody>
</table>

In our analysis, the Full advertisements were observed to be more complete as compared to the Reminder advertisements. The ‘Overall completeness’ was observed in 14 (41.2%) of the Full advertisements and 14 (10.4%) of the Reminder advertisements, respectively.

In the incomplete advertisements, as observed from the table, the ‘Date of Production of Advertisement’ was the most neglected information, followed by the ‘Marketer’s Name and Address’, in both Full and Reminder advertisements. As Date of Production of Advertisement was often missing, such advertisements could not be relied upon, in providing the latest information in that particular medical field. Also, the contact information of the marketer was often missing, which may not help the prescribing physicians in future correspondence for any cause.

For Full advertisements, the information contents, in terms of percentage completeness (present or absent), and the ‘Overall completeness’ are summarized in Figure 1.
In 6 (17.6%) Full advertisements that were incomplete in terms of ‘Marketer’s Name and Address’, marketer’s name was mentioned in all of them, but contact information in the form of marketer’s address was missing.

In Full advertisements, 1 (2.9%) advertisement was incomplete in terms of Abbreviated Prescribing Information. It was on a multivitamin formulation, which did not include the mention of the Precautions and Side-effects.

For Reminder advertisements, the information contents, in terms of percentage completeness (present or absent), and the ‘Overall completeness’ are summarized in Figure 2.

Figure 1: Information contents in Full advertisements.

Figure 2: Information contents in Reminder advertisements.
In 11 (8.2%) Reminder advertisements, the mention of the ‘Active ingredient(s)’ was absent. The advertisements included iron and multivitamin preparations, cough formulations, analgesic, antacid and antispasmodics drugs, an anti-hypertensive medication and an anti-diabetic medication.

In 39 (29.1%) Reminder advertisements, incomplete in terms of ‘Marketers Name and Address’, the marketer’s contact information in the form of address was absent in all the 39, whereas the name of the marketer was not mentioned in 1 advertisement.

Conclusion:

The low incidence of completeness of information content, in pharmaceutical advertisements, as observed in our study, indicates a lack of adherence to the advertising practices prescribed by the OPPI and the IFPMA. This trend disregards the purpose of an advertisement, of providing comprehensive information to the prescriber, necessary for making a decision. This indicates a need for mandatory regulations, to ensure the completeness of information and serve the purpose of pharmaceutical advertising in a better way.

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References: