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# Comparative Analysis of Regulatory Compliance of Printed versus Digital Drug Promotional Literature: A Cross-sectional Study.

***Radhika Sherkhane[1]*, Mahamad Ashief[2], Shashidhar Khemaji [3]***
*1 Professor of Pharmacology, SDM College of Medical Sciences and Hospital, Dharwad, Karnataka, India*
*2 Postgraduate student of MD Pharmacology, SDM College of Medical Sciences and Hospital, Dharwad, Karnataka, India*
*3 Research Assistant in Pharmacology, SDM College of Medical Sciences and Hospital, Dharwad, Karnataka, India*



## ABSTRACT

### Background

Regulatory compliance with drug promotional literature guidelines is crucial for pharmaceutical marketing. This study graded and compared the compliance of offline and online literature as per the regulatory standards.

### Methods

A quantitative, cross-sectional, comparative analysis of the promotional literature for prescription drugs available as printed copies collected from a tertiary care hospital in South India was performed with that of online literature obtained from various websites. Promotional materials for devices, supplements, and traditional medicines were excluded. A total of 250 (130 offline and 120 online) pieces of literature were analyzed by using a harmonised 11-item checklist based on World Health Organization and the Uniform Code for Pharmaceutical Marketing Practices 2024 guidelines to assess core drug information, safety data, and scientific substantiation as provided by the regulatory bodies. Data were analyzed using descriptive statistics and Pearson's Chi-square test, with $p < 0.05$ considered statistically significant.

### Results

Of the 130 printed and 120 digital literatures, most were classified as Grade B, with printed ones demonstrating better overall compliance than digital material (Grade A: 9.2% vs. 0%; Grade C: 6.2% vs. 27.5%). Printed leaflets were significantly more likely to include dosage forms and precautions, whereas online material had more frequently mentioned therapeutic indications ($p < 0.05$). Safety information, including adverse drug reactions, contraindications, drug interactions, and scientific references, was inadequately reported in both groups.

### Conclusion

These findings indicate that clinicians should exercise critical scrutiny rather than implicit trust while evaluating pharmaceutical promotional claims. To bridge this quality gap, there is a need for a dedicated oversight body to monitor regulatory compliance, alongside a greater commitment to veracity from pharmaceutical manufacturers.

### Recommendations

Future research must focus closely on establishing post-UCPMP compliance behaviour, evaluating the direct influence of DPL quality on clinician prescribing behaviour, and integrating ethical promotion principles into graduate medical education.

***Keywords:*** *Drug promotional literature, Online promotional literature, drug promotional leaflet, Pharmaceutical Marketing, Drug Promotion, Pharmaceutical product claims, Uniform Code for Pharmaceutical Marketing Practices, Regulatory compliance*
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***Corresponding author:*** *Dr. Radhika Sherkhane*
***Email:*** ***drradhika78@gmail.com***
*Department of Pharmacology, SDM College of Medical Sciences and Hospital, Dharwad, Karnataka, India*

## Background of the study

The pace of growth in new drug approvals has seen a sharp uptick in the past two decades. (1) This can be attributed to the consistent efforts being made by researchers to explore novel pharmacological pathways and also to the competition among the pharmaceutical companies to dominate the market. (2,3)

With this growing trend, it becomes imperative for clinicians to be constantly updated with these drugs and their clinical profiles. (4) Many medical practitioners have an

extremely busy schedule because of the workload, especially in a country like India. Hence, they have less time to update their knowledge through continuing medical education lectures and thus rely on DPLs to get information about new developments in therapeutics. (5)

An important method used by the pharmaceutical companies to inform and influence the physicians about drugs is the drug promotional literature (DPL). (6) Historically, offline DPLs in the form of brochures, handouts, and pamphlets played the central role in disseminating information on drugs. (7) However, with the boom of telemedicine, social media platforms, online engagement of the physicians and sheer easy to access the drug info, online DPLs put out by pharmaceutical companies have grabbed an equal space in this arena. (8)

Drug promotion must be done ethically to avoid false information. (9) At a global level, WHO has laid down ethical guidelines to this effect at a global level and national level. (10)

While previous published studies of DPLs have predominantly focused on printed media, a significant knowledge gap persists regarding the regulatory alignment of digital materials. This study directly addresses this empirical gap by conducting a rigorous comparative analysis of DPLs sourced from both print and online platforms.

Previously, it was the OPPI (Organisation of the Pharmaceutical Producers of India) guidelines, a private firm guideline, that were followed in India. (11) Recently, in 2024, the Government of India mandated the new UCPMP guidelines to regulate the quality of DPLs at a National level. (12) This study uses these new guidelines along with the global WHO guidelines to assess the DPLs.

Evaluating the veracity of DPLs is essential to public health, given that inaccurate promotional material frequently correlates with irrational clinical prescribing and subsequent healthcare inefficiencies. (13) This investigation intends to optimize standard norms by equipping the stakeholders with data-driven insights into systemic compliance gaps across print and digital media and pave the way for future large-scale studies in this area.

## Methods

### Study design

A quantitative, cross-sectional, comparative analysis of DPLs for prescription drugs. This study received approval from the Institutional Ethics Committee of SDM College of Medical Sciences and Hospital, Dharwad. Karnataka. India (reference number: SDMIEC/2025/1086 dated 31.10.2025).

### Study setting

DPLs were collected from out-patient departments (OPDs) of the Department of General Medicine, dermatology, psychiatry, pulmonology, paediatrics, general surgery, obstetrics and gynaecology, ophthalmology, otorhinolaryngology, orthopaedics, and in-patient departments (IPDs) of all sections of SDM College of Medical Sciences and Hospital, Dharwad. Karnataka. India, wherever available for printed DPLs during the study period of 3 months from November 2025 to January 2026 to ensure a diverse sample.

The digital DPLs were collected from websites during the study period. Printed and digital DPLs were sampled separately.

Printed DPLs: eligible printed promotional materials were prospectively collected from the outpatient and inpatient departments of the study hospital during a three-month study period. The materials included printed promotional materials such as flyers, brochures, and journal advertisements intended for healthcare professionals. Each distinct promotional item was treated as one unit of analysis. Duplicate copies of the same promotional material were excluded, and unique DPLs designated with a unique identification code were retained for analysis.

Digital DPLs: 120 digital DPLs were identified through a structured search of publicly accessible websites of pharmaceutical companies operating in India, professional medical platforms, and online promotional or sponsored content.

Searches were conducted during the study period using combinations of search terms related to prescription drug promotion, including 'drug promotional literature', 'drug promotion ', 'prescription drug promotion ', 'pharmaceutical advertisement ', 'online drug promotion ', 'digital drug promotion ', 'pharmaceutical promotional material ', and 'pharmaceutical sponsored content'. Retrieved materials were screened according to the predefined eligibility criteria. Where identical promotional material was identified on more than one webpage or platform, it was considered a duplicate and counted only once. Each eligible unique digital DPL was assigned a unique identification code.

Offline DPLs identified → screened → duplicates removed → eligibility assessment → 130 included
Online DPLs identified → screened → duplicates removed → eligibility assessment → 120 included

Thus, out of a total of 286 DPLs collected, 36 duplicates (14 printed and 22 online) were excluded, and a total of 250 unique DPLs were included in the final analysis.

### Inclusion criteria

All accessible printed and digital DPLs for prescription drugs aimed at healthcare professionals in India.

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## Exclusion criteria

Promotional materials for medical devices, nutritional supplements, and traditional medicines were excluded.

## Statistical analysis

Each DPL was independently evaluated using a harmonised 11-item promotional information compliance checklist (Table 1) developed from the WHO Ethical Criteria for Medicinal Drug Promotion and UCPMP 2024 guidelines.

The checklist included the presence or absence of essential promotional components, including brand name, active ingredient, dose, dosage form, therapeutic indication, precautions and warnings, adverse drug reactions, contraindications, drug interactions, manufacturer details and scientific references.

Each fulfilled criterion was assigned one point, giving a maximum compliance score of 11 and a minimum score of 0. These 11 variables represented consolidated assessment domains derived from the relevant WHO and UCPMP requirements. The 11-point score was not intended to represent 22 separately scored criteria. Rather, it was a harmonized 11-domain promotional information-compliance score developed for comparative assessment of the DPLs. Requirements that did not correspond to one of the 11 predefined scoring domains were not assigned additional points.

Based on the total score, DPLs were categorized into three grades:

- Grade A: 9 to 11 points
- Grade B: 5 to 8 points
- Grade C: 0 to 4 points

The frequency of each promotional component was compared between offline and online DPLs.

Data were entered into Microsoft Excel and checked for completeness and consistency before analysis.

Categorical variables were summarized using frequency and percentage. Differences between offline and online DPLs for each promotional component were analyzed using Pearson's Chi-square test. Fisher's exact test was used wherever the expected cell frequency was less than five. Statistical significance was set at $p< 0.05$.

## Results

A total of 250 DPLs were evaluated, of which 130 (52%) were collected from offline sources and 120 (48%) from online sources.

**TABLE-2 OVERALL INFORMATION COMPLIANCE OF PRINTED AND DIGITAL DPLs**

| | Grade A | Grade B | Grade C |
|---|---|---|---|
| **Offline** | 12 | 110 | 8 |
| **Online** | 0 | 87 | 33 |

$\chi^2 = 29.58$, df = 2, $p < 0.001$

**TABLE-1. THE 11-ITEM PROMOTIONAL INFORMATION-COMPLIANCE CHECKLIST AS PER THE WHO CRITERIA AND UCPMP 2024 REQUIREMENTS**

| No. | Scoring domain | Corresponding WHO criterion | Corresponding UCPMP 2024 criterion | Scoring |
|---|---|---|---|---|
| 1 | **Brand name** | WHO 2: Brand name should be provided | UCPMP 2: Name of the drug | 1 |
| 2 | **Active ingredient/generic name** | WHO 1: Name of active ingredient(s) using INN/approved generic name | UCPMP 3: List of active ingredients; UCPMP 4: Generic name adjacent to prominent drug name | 1 |
| 3 | **Dose** | WHO 3: Content of active ingredient per dosage form/regimen | UCPMP 5: Recommended dosage | 1 |
| 4 | **Dosage form/regimen** | WHO 6: Details of dosage form or regimen | UCPMP 6: Method of use and, when not obvious, method of administration | 1 |
| 5 | **Therapeutic indication/use** | WHO 5: Approved therapeutic uses | — | 1 |
| 6 | **Precautions and warnings** | WHO 8: Precautions, contraindications and warnings | UCPMP 8: Warnings and precautions for use | 1 |
| 7 | **Adverse drug reactions** | WHO 7: Side effects/major adverse drug reactions | UCPMP 7: Adverse reactions | 1 |
| 8 | **Contraindications** | WHO 8: Precautions, contraindications and warnings | UCPMP 9: Relevant contraindications | 1 |
| 9 | **Drug interactions** | WHO 9: Major drug interactions | — | 1 |

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| | | | | |
|---|---|---|---|---|
| 10 | **Manufacturer/authorization-holder details** | WHO 10: Name and address of manufacturer/distributor | UCPMP 1: Name and address of holder of authorization | 1 |
| 11 | **Scientific references** | WHO 11: Reference to scientific literature, as appropriate | — | 1 |
| | **Maximum score** | | | **11** |

*Data entered in the extraction checklist based on WHO and UCPMP guidelines were analyzed. (Table-1)*

WHO and UCPMP requirements addressing substantially overlapping promotional information were mapped to a single scoring domain to avoid double counting. The 11-domain score was developed for comparative content assessment and did not assign separate points to every individual provision of the two frameworks. WHO criterion 4 (names of ingredients known to cause problems), UCPMP criterion 10 (statement that additional information is available on request), and UCPMP criterion 11 (date of generation/last update) were not represented as separate domains in the 11-point scoring system and therefore did not contribute additional points to the total score.

## Overall Information Compliance

Based on the overall promotional information compliance, most DPLs in both groups were classified as Grade B. Among offline DPLs, 110 (84.6%) were Grade B, 12 (9.2%) were Grade A, and 8 (6.2%) were Grade C. In comparison, 87 (72.5%) online DPLs were Grade B, while 33 (27.5%) were Grade C based on the 11-item promotional information-compliance score. None of the online DPLs achieved Grade A compliance, and none of both the types either had Grade 0 compliance. These findings indicate better overall adherence to standard criteria among offline promotional materials than their online counterparts. (Table-2)

## Comparison of Individual Promotional Components

**TABLE 3- COMPARISON OF INDIVIDUAL PROMOTIONAL COMPONENTS IN PRINTED AND DIGITAL DPLs**

| Component | Offline (%) (n=130) | Online (%) (n=120) | p-value |
|---|---|---|---|
| **Brand name** | 130 (100.0) | 120 (100.0) | |
| **Active ingredient** | 127 (97.7) | 118 (98.3) | 1.000 |
| **Dose** | 116 (89.2) | 108 (90.0) | 1.000 |
| **Dosage form/regimen** | 107 (82.3) | 82 (68.3) | 0.015* |
| **Therapeutic use** | 68 (52.3) | 98 (81.7) | <0.001* |
| **Precautions/Warnings** | 16 (12.3) | 5 (4.2) | 0.037* |
| **Adverse drug reactions** | 5 (3.8) | 1 (0.8) | 0.254 |
| **Contraindications** | 4 (3.1) | 1 (0.8) | 0.416 |
| **Drug interactions** | 8 (6.2) | 1 (0.8) | 0.055* |
| **Manufacturer/authorization-holder details** | 114 (87.7) | 101 (84.2) | 0.535 |
| **Scientific references** | 29 (22.3) | 19 (15.8) | 0.255 |

Regarding the frequencies of individual promotional components in offline and online DPLs (Table-3), both offline and online DPLs consistently mentioned the brand name (100%), active ingredient (97.7-98%), and dose (89-90%), with no statistically significant differences between the two groups ($p > 0.05$).

Offline DPLs were significantly more likely to mention dosage form than online DPLs (82.3% vs. 68.3%; $p = 0.015$). Conversely, online DPLs more frequently included the therapeutic use of the promoted drug compared to offline DPLs (81.7% vs. 52.3%; $p < 0.001$).

Safety-related information remained inadequately reported in both groups. However, offline DPLs were significantly more likely to include precautions and warnings than online DPLs (12.3% vs. 4.2%; $p = 0.037$).

Although adverse drug reactions, contraindications, drug interactions, and scientific references were reported more frequently in offline DPLs, these differences were not statistically significant ($p > 0.05$). The Manufacturer details were also comparable between the two groups.

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## Discussion

The primary objective of this study was to compare the regulatory and promotional information compliance of printed and digital prescription-drug promotional literature as given by the regulatory authorities WHO and UCPMP. The DPLs were compared using the harmonised 11-item promotional information compliance checklist (Table-1) created by unifying items from the two regulatory formats. Our findings demonstrate that while most DPLs achieved middle-ground compliance (Grade B), offline materials exhibited better overall adherence to their online counterparts as per the 11-item checklist. Notably, no online DPLs achieved Grade A status, and over a quarter fell into the lowest compliance category (Grade C) (Table-2). Furthermore, essential safety-related information was infrequently reported across both formats.

Most of the studies exploring the DPLs have been centred on the printed promotional material supplied by the manufacturing companies to the practicing doctors. (5-9,14,15) Scarce literature is available on the evaluation of DPL campaigns online by the manufacturers. The few studies published have either the DPLs promoted through social media channels or have a very sparse sample size. (16,17,18).

The present study provides a snapshot of current drug promotional practices in India, highlighting a concerning gap between ethical guidelines and their real-world implementation. Analysis of individual promotional components (Table-3) revealed that fundamental product information—such as brand name, active ingredient, and dose was consistently provided at high frequencies in both offline and online DPLs. This is expected, as these details are essential for product identification and marketing. However, the inclusion of information supporting rational prescribing remained unsatisfactory. Core safety elements such as precautions and warnings, adverse drug reactions, contraindications, and drug interactions were consistently underreported (Table-3).

Although most of the DPLs- both offline and online- were categorized as Grade B. This middle-ground compliance reflects selective adherence rather than comprehensive ethical conduct. As highlighted by previous literature, the offline printed DPLs contained imbalanced information. (4,5,13). However, in the present study, the higher frequency of therapeutic-use information was noted in online DPLs (81.7% vs. 52.3%), together with the relatively low frequency of safety information, which may reflect an imbalance in the informational content of these materials. However, the present study cannot determine whether this pattern reflects a deliberate emphasis on benefits by the manufacturers.

Given that DPLs often serve as quick reference tools rather than exhaustive scientific documents, omission or limited presentation of risk-related information could reduce the informational balance available to clinicians. This asymmetry is particularly problematic given the increasing reliance of healthcare professionals on digital content owing to time constraints and the convenience of online platforms. Such asymmetry may influence prescribing behaviour, especially among clinicians with limited time for independent literature reviews.

The introduction of the UCPMP 2024 guidelines marks a critical shift from voluntary to government-mandated regulations. The compliance grading used in this study reflects adherence to the harmonised 11-item promotional information compliance domains derived from the WHO Ethical Criteria and UCPMP 2024 and should not be interpreted as a comprehensive determination of legal or regulatory compliance with every provision of either framework. The findings of this study serve as important baseline data against which future compliance can be measured. By systematically identifying contemporary informational gaps, this research can contribute to the refinement of frameworks that govern the ethical integrity of DPLs. Strengthening enforcement and monitoring mechanisms, particularly for digital promotional content, is essential to ensure balanced, evidence-based drug promotion.

This study highlights the potential for misleading promotional information to induce irrational prescribing patterns, thereby compromising patient safety and straining healthcare delivery systems.

In conclusion, this study demonstrates a significant discrepancy between current pharmaceutical marketing practices and established ethical benchmarks, especially within emerging digital landscapes.

## Generalizability

The offline DPL results reflect promotional practices within a single tertiary care teaching hospital setting, which may not fully represent materials distributed in primary care, private clinics, or non-academic settings. The online findings are generalizable primarily to publicly accessible digital pharmaceutical platforms operating during the specific study period, recognizing that digital promotional content is highly dynamic.

## Limitations

Offline sampling was restricted to a single-centre tertiary hospital setting, while online sampling depended on public accessibility and platform visibility, which can be influenced by differential digital availability. As promotional practices and digital content are dynamic, the three-month collection period limits temporal generalizability and may not capture broader variations in promotional materials.

While duplicate promotional materials were identified and excluded, the duplicate detection process may have missed highly similar but non-identical promotional materials.
Finally, the compliance grading used in this study reflects adherence to the 11-item checklist promotional information domains derived from the WHO Ethical Criteria and UCPMP 2024. It should not be interpreted as a comprehensive determination of legal or regulatory compliance with every provision of either framework.

## Author Contributions

Radhika Sherkhane: Conceptualization, Investigation, Writing – original draft, Writing – review & editing, Project administration.
Mahamad Ashief: Investigation, Writing – original draft.
Shashidhar Khemaji: Investigation, Formal analysis.
Dr Radhika Sherkhane is the corresponding author.

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## Professional Medical Writer Declaration

The authors declare that no professional medical writing, editing assistance, or automated language generation tools were utilized in the preparation, drafting, or editing of this manuscript. The entire work was conceived, analyzed, and written solely by the listed authors.

## Conflict of interest

The authors declared no conflict of interest regarding the publication of this paper.

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## Data availability

Data is available upon request.

## List of abbreviations

Drug promotional literature- **DPL**
World Health Organization- **WHO**
Uniform Code for Pharmaceutical Marketing Practices- **UCPMP**
Organisation of the pharmaceutical producers of India- **OPPI**
Out-patients departments- **OPDs**
In-patient departments- **IPDs**
Adverse Drug Reaction- **ADR**

## Author Biography

Radhika MS is a Professor of Pharmacology at SDM College of Medical Sciences and Hospital, Dharwad, Karnataka, India.
Mahamad Ashief is a postgraduate resident student of MD Pharmacology at SDM College of Medical Sciences and Hospital, Dharwad, Karnataka, India.
Shashidhar Khemaji is a research assistant at SDM College of Medical Sciences and Hospital, Dharwad, Karnataka, India.

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