# Evaluation Of The Rationality Of Claims Made In Drug Promotional Literature In West Chennai




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# Drug Promotional Literature

WHO defines promotion

"to all the informational and persuasive activities of manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase and / or use of medicinal drugs"

# Cont.….




- Primary goal of pharmaceutical advertisements is to convince physicians to prescribe the manufacturer's product.
- Should provide relevant research findings regarding the drug.
- Important source of prescribing information to the doctor.

# Cont.….

- The pharmaceutical companies target prescribers through
  - ❖ weekly or monthly visits,
  - ❖ distributing samples &
  - ❖ **attractive, eye-catching brochures**

which are most often misleading and confusing.

- Improper advertisement of drugs encourages **drug consumerism** instead of the rational use of

# Ethical Guidelines For Drug Promotion

## International Level.

- Ethical criteria for medicinal drug promotion by World Health Organization

WHO




- Code of Pharmaceutical Marketing Practices by International Federation of Pharmaceutical Manufacturers Association

IFPMA



# Cont.….

## India

Organization of Pharmaceutical Producers of India OPPI

self-regulatory code of pharmaceutical marketing prac-tices.

# Aims and objectives:

To evaluate drug promotional literature as per

- World Health Organization (WHO) Criteria,
- Quality of Coverage,
- Types of Claims,
- Genuineness of Scientific Information.

This evaluation would help physicians to find out as to **what extent**

# Materials and Methods:

- 412 drug promotional literatures **(brochures)**
- Outpatient Department (OPD)
- 20 busy physicians
- Western part of Chennai
- Period of 1 month - **1st June to 30th June 2014**

# Inclusion criteria:

- promoting modern medicines,
- making at least one therapeutic claim

were included in this study

# Exclusion criteria

Literatures promoting

- Medicinal Devices,
- Medical Equipment's,
- Orthopedic Prosthesis,
- Product Monographs,
- Ayurvedic Medicines,
- Re-minder Advertisements

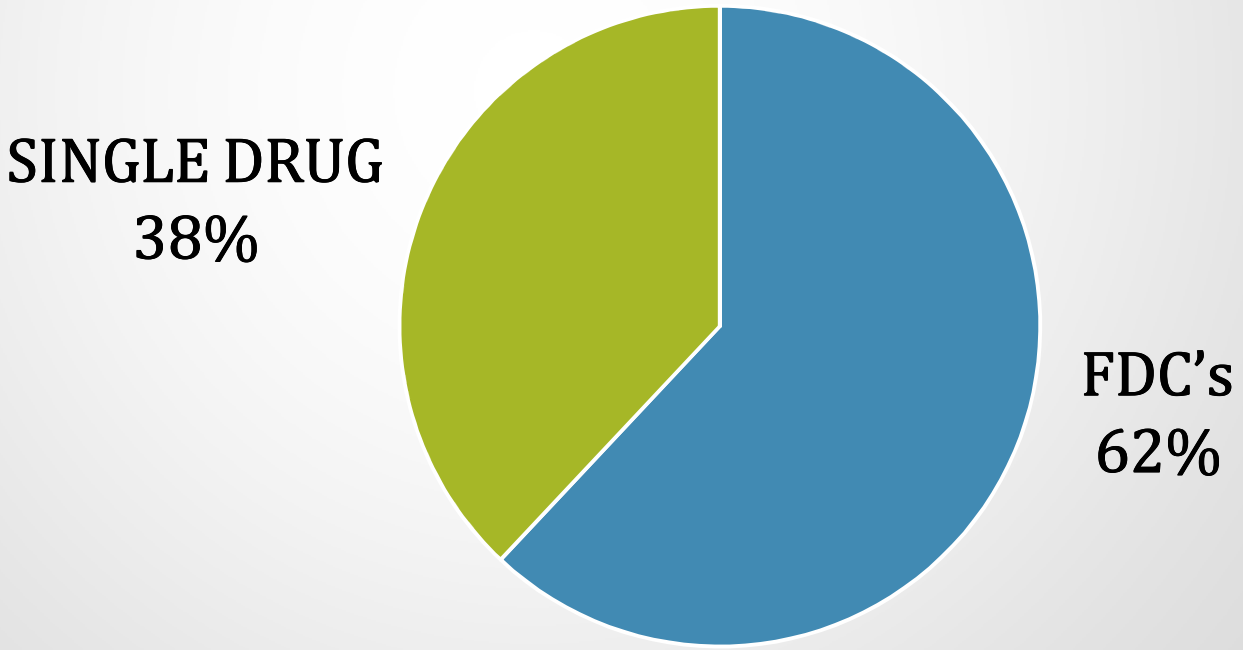
were excluded from the analysis

# Cont.….

- **Adequacy Of Coverage -** Ethical medicinal drug promotion criteria by WHO.
- **Quality Of Literature -** A pre-tested and pre-validated checklist with nine parameters.
- **Genuineness Of Scientific Information-** literature were cross checked by referring to standard literature online, listed in databases like PubMed, Medline and Cochrane reviews, standard text books and peer reviewed journals.

# Results

Total of **486 drugs** were presented in 412 drug promotional literatures



# Types Of Drugs Promoted

Most commonly promoted group of drug was

**Cardiovascular drugs 112 (23%)**

followed by

- Nutritional supplements 83 (17%),
- Miscellaneous 59 (12.1%),
- Antibiotics 56 (11.6%),
- Hormones & antidiabetics 48 (9.8%),
- Obstetrics & Gynecology 41 (8.4%),
- NSAID's drugs 35 (7.2%),
- Gastrointestinal Tract drugs 32

# Adequacy of Coverage – WHO

| CRITERIA | NUMBER OF SAMPLES | MENTIONED (%) |
|---|---|---|
| INN | 409 | 99.27 |
| Brand Name | 412 | 100 |
| Content of active ingredient(s) | 359 | 87.1 |
| Adjuvant | 5 | 1.21 |
| Approved therapeutic uses | 393 | 95.3 |
| Dosage form or Regimen | 365 | 88.6 |
| Side effects & adverse reactions | 37 | 9.8 |
| Precautions, contraindications | 34 | 8.25 |
| Major interactions | 22 | 5.33 |

# Cont.….

- None of the brochures fulfilled all the 11 WHO criteria
- Brand name was mentioned in all the drug promotional literature, whereas the generic name was found in 409 literature
- 376,(91.2%) of leaflets satisfied the 4 WHO criteria,
  - Brand Name,
  - Generic Name,
  - Approved Therapeutic Uses,

# Cont.….

- Approved therapeutic use of the drug was mentioned in 393 (95.3%) drug promotional literatures.
- Most neglected aspects (<10%) of drug promotion was information about
  - Drug Interactions,
  - Precautions,
  - Adverse Drug Reactions

# Quality of Coverage

| PARAMETER | NUMBER OF SAMPLES | n=41(%) | n=67 (16.2%) (%) |
|---|---|---|---|
| Drug to drug comparison | 51 | 12.38 | 76.12 |
| Random Assignment | 36 | 8.74 | 53.73 |
| Blinding status | 29 | 7.04 | 43.28 |
| *"P"* value given | 44 | 10.68 | 65.67 |
| Comparability of groups | 3 | 0.73 | 4.8 |
| All accounted for or ITT | 4 | 0.98 | 5.97 |
| ARR /NNT reported | 31 | 7.52 | 46.27 |
| Power mentioned | 6 | 1.46 | 8.95 |

# Cont.….

- Pharmaceutical companies also made **multiple claims** in the literature, apart from giving therapeutic information.
- Average two claims were made per literature i.e. 954 claims were made in 412 drug promotional literature (**2.31 per literature**).
- Claims about efficacy were made in 91% of the literatures.
- References were cited in 47% of the literature of which **96% were from indexed journal**

# Genuineness Of Scientific Information

| PARAMETER | NUNBER OF SAMPLES | PERCENTAGE (%) |
|---|---|---|
| Authentic | 123 | 29.9 |
| Exaggerated | 114 | 27.67 |
| Controversial | 95 | 23.1 |
| Misrepresentation | 52 | 12.62 |
| | | |

# Cont.….

| ACTIVE INGREDIENT | CLAIMS MADE | VALUE OF THE CLAIM |
|---|---|---|
| Ondansetron | Nausea & vomiting of pregnancy: 1st choice | Exaggerated claim |
| Nebivolol | Safe in diabetes | Authentic claim |
| Ranitidine | 1 mon to 16 yrs. safe | Authentic claim |
| Doxylamine | No adverse event | False claim |
| Calcium & Vitamin D3 | Correct vitamin D deficiency & help reduce cardiovascular risk | Misrepresentation of data from standard literature |
| Olmesartan | Only ARB providing | Exaggerated claim |

# Discussion

## Observation:

- Therapeutic information given in the literatures were more **biased** to selling the drug than to help physicians reach a rationalized decision about the drug that was being promoted.
- There was more of a **commercial relationship** between the prescriber and the pharmaceutical company, in the drug

# Cont.….

- There is evidence that these kinds of drug promotional practices can **negatively affect** both patients and the health care professionals.
- The literatures were full of claims regarding safety or efficacy that were not supported with proof or rather unsubstantiated, and certain claims were therapeutically irrelevant also

# Cont.….

- Therapeutically irrelevant information was printed, **compromising space** that would have been used to cite more important scientific information.
- Quality of **paper, print, and color** were excellent in all (100%) literatures.

# Drawbacks observed in this study

- In most of the literatures, the **generic name was mentioned in small letters** than the brand name.
- Price of the drug was not mentioned in most of the literatures
- Most neglected aspects (<10%) of drug promotion was
  - Drug Interactions,
  - Precautions,
  - Adverse Drug Reactions

# In India

Ethical committees for monitoring unethical drug promotion

Physicians have moral responsibility for filing a complaint about the flaws to the concerned authority

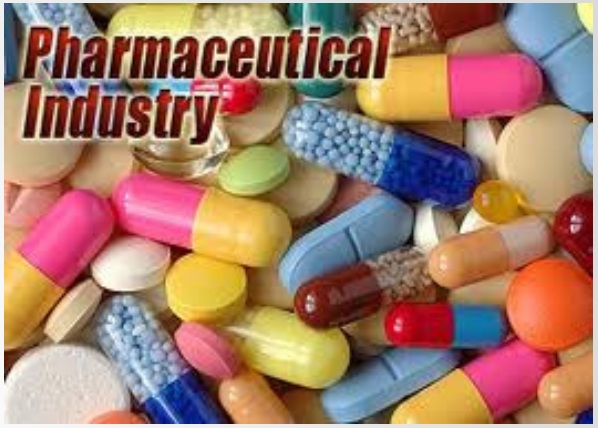
Drug controller authority to take necessary action on complaints received

# Conclusion

- Drug promotional literature analyzed in this study was **inadequate in terms of their adequacy, quality and genuineness of coverage**
- Hence, it can be concluded that the majority of the drug promotional literatures that are given to the prescribers are **not able to spread awareness** towards rational prescribing,








# Ethical promotion of a drug & rational prescribing



# References:


- Ethical criteria for medicinal drug promotion. World Health Organization – http://www.who.int
- Evaluation of rationality of promotional drug literature using World Health Organization guidelines. Indian J Pharmacology – Mali SN
- International Federation of Pharmaceutical Manufacturers & Associations http://www.ifpma.org
- The availability of references and the sponsorship of original research cited in pharmaceutical advertisements – Cooper RJ

# Thank you


MOLIBOSE MGT
Zoxakind-O
(Ofloxacin 50 mg + Nitazoxanide 100 mg) / 5 ml
Zanocin Plus
Ofloxacin 200mg + Cefixime 200mg Tablets
Pamamol
Pamabrom 25mg + Paracetamol 325mg
Extra relief in PMS
MDR TYPHOID
PHARYNGITIS
TONSILLITIS
UTIS
BREAK THRU K
PERFORMANCE
ZIPOD
RACIPER D 20
Cofstop-Z
Inhibits the Virus Reduces the Cough
Doxozet - 400
Doxofylline 400mg Tablets
Provides undisturbed sleep in COPD
In Asthma
In COPD
Montair
Non-steroidal anti-inflammatory
Oral
Once daily
Asthma controller
nurture
Moxikind-CV 625
Movacobal 5 SR
Methycobalamin 5 mg Sustained Release tablets
Protects brain against neurotoxins
Enhances brain cell methylation
Inducts B12 in CSF
Helps in the management of Chronic fatigue syndrome & fibromyalgia
Helps in Oligospermia & Oligozoospermia
Movacobal 5 SR
High strength mecobalamin for higher response
MOVA PHARMACEUTICALS PVT. LTD.
Clock Time