

## OTC Marketing of Drugs

*Vijay Bhangale\**

### Introduction

#### OTC Drugs

‘OTC Drugs’ means drugs legally allowed to be sold ‘Over The Counter’, i.e. without the prescription of a Registered Medical Practitioner. In India, though the phrase has no legal recognition, all the drugs that are not included in the list of ‘prescription drugs’ are considered as non-prescription drugs (or OTC drugs). Prescription Drugs are those that fall under two schedules of the Drug and Cosmetics Rules, 1945: Schedule H and Schedule X. Drugs falling under Schedule G require the following mandatory text on the label: “Caution: It is dangerous to take this preparation except under medical supervision” and hence are not advertised to the public voluntarily by the industry.

In India, the import, manufacture, distribution and sale of drugs and cosmetics are regulated by the Drugs and Cosmetics Act (DCA) and its subordinate legislation, the Drugs and Cosmetics Rules (DCR).

#### Ayurvedic Medicines

OTC proprietary drugs which are registered as ‘Ayurvedic Medicines’ (traditional Indian medicines containing natural / herbal ingredients) are also regulated by the DCA and DCR. However, they do not require a drug licence and can therefore be sold by non-chemists. There is no price control on ‘Ayurvedic medicines’.

Some of the top OTC brands in India such as Vicks VaproRub, Amrutanjan Balm, Zandu Balm, Iodex, Moov Pain Cream, Itch Guard Cream, ENO Fruit Salt, Vicks Cough Drops, Halls Lozenges, etc., are registered as ‘Ayurvedic Medicines’ because of their plant-based natural active ingredients.

Considering the above framework, key categories with OTC potential in India would be:

- Vitamins and minerals
- Cough and cold
- Gastrointestinals
- Analgesics /Dermatological

#### Marketing authorization

The major source for pharmaceutical regulation is the Drugs and Cosmetics Act (DCA) and its subordinate legislation, the Drugs and Cosmetics Rules (DCR). This legislation applies to the whole of India and to all sorts of medicines (e.g. allopathic, ayurvedic, homeopathic, etc.) whether imported or made in India. The legislation is enforced by the Central Government (Ministry of Health & Family Affairs) in New Delhi, which is responsible for its overall supervision. The office of the Drugs Controller General of India (DCGI) has prime responsibility for approving all new molecules and unique new formulations. However, power to provide manufacturing and selling licenses which are the two main registrations required to manufacture and sell a drug – belongs to each individual State government through its Food and Drug Administration (FDA), who also carry out enforcement of DCA and DCR. Matters of new molecule approval and standards, clinical trials, introduction of a new unique formulation and import licenses are handled by the DCGI.

Note: The OTC Committee of the Organisation of Pharmaceutical Producers of India (OPPI) is working towards the promotion of responsible self-medication with a view to growing the OTC sector. It is aiming to get regulatory support for issues such as the accessibility of household OTC remedies and increasing the awareness of the importance of responsible self-medication with the general public and the Government.

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\* 402, Shubh Apartment, Opp.Kelkar College, 90 ft.Road, Mulund (E), Mumbai – 400 081.

### **Advertising to the general public**

The Drug & Magic Remedies (Objectionable Advertisement) Act mentions a list of ailments for which no advertising is permitted. It also prohibits misleading advertisements, which, directly or indirectly, give false impressions regarding the true character of the drug; make false claims, or are otherwise false or misleading in any particular respect. The DCGI's office –in collaboration with OPPI -has released a Voluntary Code on OTC Advertising, which is being followed by all OPPI member companies.

Currently, there is no specific law, which prohibits the advertising of prescription drugs although industry practice is not to advertise prescription-only drugs. The DCGI's office is considering coming out with a notification prohibiting the advertising of any drug, which legally requires a doctor's prescription for its purchase.

The following OTC medicines advertising can be seen on TV in India:

- Digestives
- Antacids
- Antiflatulents
- Cold rubs and analgesic balms/creams
- Vitamins/tonics/health supplements (especially herbals and Ayurvedic-registered)
- Medicated skin treatment
- Analgesic/cold tablets
- Antiseptic creams/liquids
- Glucose powders
- Cough liquids
- Throat lozenges
- Medicated dressing (band-aids)
- Baby gripe water.

### **Distribution**

There is at present no system of national chains of supermarkets or drugstores / pharmacies, and small independent shops dominate retailing. However, a few chains such as Apollo Pharmacy, Medicine Shoppe, and Good Health etc. are entering the market, which will make inroads all over India in the near future. Typically however, less than 5% of sales of FMCG manufacturers currently (in 2006) go through organized retailers.

### **Pricing**

Price controls are carried out on certain drugs by virtue of the Drugs (Prices Control) Order 1995 (DPCO), under the Essential Commodities Act (ECA). The DPCO is the responsibility of the Ministry of Chemicals and Fertilisers and is supervised by the National Pharmaceutical Pricing Authority (NPPA). It outlines the classification of price-controlled products and methods of price fixation and revision. The NPPA monitors the prices by fixing and revising prices of drugs. Only a few OTC actives, e.g. acetylsalicylic acid and ephedrine & its salts, fall under current DPCO price control.

### **Market data on OTC medicines**

India is currently ranked 11<sup>th</sup> in the global OTC market in size, with an estimate that it will reach 9<sup>th</sup> position within five years.(Source :Nicholas Hall & Company,India,DB6 2006)

Currently the Indian OTC market (i.e. non-prescription advertised medicines) is estimated to represent approximately Rs.104 Billion growing at about 8-9% (Source :ORG-IMS)

### **Prescription to OTC Switch**

Though not yet a pill-popping country, India is inching the OTC way. Indian OTC healthcare is in nascent stages and ranks 11<sup>th</sup> in the global OTC market. But, urban India is catching up with the concept, thanks to the advent of technology, improving literacy levels, increasing health awareness and high work stress levels. In fact, Indian consumers, today, are confident about sharing healthcare responsibility, especially in case of common ailments. Considering the changing mindset and likely changes in regulatory framework, such as, OTC guidelines and open distribution, it is reasonable to estimate that within the next ten years, India will become a major contributor to the world of OTC market.

Currently, aches/pains, cough, colds, hyperacidity, minor topical infections, and indigestion are major OTC categories. Emerging categories include cuts, wounds and burns, muscle pains and sprains, diarrhea and constipation. There are many Prescription products, which could be revitalized through OTC switches. An analytical interpretation of various data placed the focus on vitamins, cough & cold, antacids, antipyretics and NSAIDs as opportunity areas for switch in India.

However, the big issue in OTC marketing is not the switch climate as currently even drugs, which do not require a prescription, are promoted via the doctor because

- a) Marketing through medical representatives is less expensive than mass media advertised marketing. This makes proprietary medicines higher priced than equivalent ethically promoted drugs.
- b) Practically all prescription drugs can be purchased without prescription.
- c) Doctor influence is strong in patient purchase behaviour.
- d) Distribution of OTC allopathic medicines is limited to drug licensed stores (mainly pharmacies).

### **Problem**

1. Determine the extent of Self Medication & Consumer attitudes towards OTC medicines
2. Seek Opinion of Medical Professionals on promotion of OTC Drugs
3. Identify key Influences on purchases of OTC medicines by consumers

### **Methodology**

1. Gather secondary data on marketing of OTC medicines from books, magazines, research articles, and websites
2. Survey of Consumers, Doctors and Retailers, a structured questionnaire being administered to the respondents

### **Sampling**

#### *1. Sampling unit:*

- Experienced Doctors (General practitioners as well as consultants) selected from different parts of Mumbai as per the convenience
- Retailers (Chemists) selected from different parts of Mumbai
- Consumers (male, female above 18 yrs) selected from different parts of Mumbai

#### *2. Sample size:*

- Doctors – 100
- Retailers - 50
- Consumers – 100

#### *3. Sampling procedure:*

- Stratified Random Purposive Sampling

**Contact Method**

- Personal Interview

**Data Analysis Tool**

- SPSS – Cluster Analysis

**Study Limitations**

- Only Mumbai based, so not representative of entire country

**Data Analysis**

- **Willingness of Consulting Physicians to prescribe OTC medicines**

**Statistics**

Dr, do you prescribe OTC medicines

N	Valid	50
	Missing	0

**Consulting Physicians prescribing OTC medicines**

	Frequency	Percent	Valid Percent	Cumulative Percent
Valid yes	19	38.0	38.0	38.0
no	31	62.0	62.0	100.0
Total	50	100.0	100.0	

- **Willingness of GP's to prescribe OTC medicines**

**Statistics**

Dr, do you prescribe OTC medicines

N	Valid	50
	Missing	0

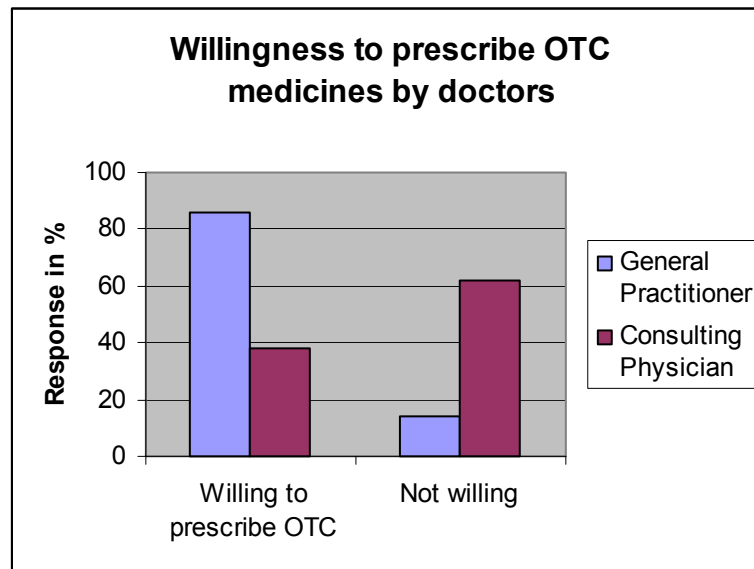
**General Practitioners (GPs) prescribing OTC medicines**

	Frequency	Percent	Valid Percent	Cumulative Percent
Valid yes	43	86.0	86.0	86.0
no	7	14.0	14.0	100.0
Total	50	100.0	100.0	

- **Willingness to prescribe OTC medicines by Consulting Physicians and GPs**

		Specialty of doctor			
		Consulting physician		GP	
		Count	Col %	Count	Col %
Dr, do you prescribe OTC medicines	yes	19	38.0%	43	86.0%
	No	31	62.0%	7	14.0%
Total		50	100.0%	50	100.0%

- **Willingness to prescribe OTC medicines**



Majority of doctors are willing to prescribe OTC medicines, predominantly the General Practitioners (GP's).

- **Most favored category for OTC medicines**

**Statistics**

Most favored category for OTC

N	Valid	100
	Missing	0

Most favored category for OTC

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Muscle pain	21	21.0	21.0	21.0
	Cuts & burns	6	6.0	6.0	27.0
	Diarrhea	9	9.0	9.0	36.0
	Constipation	11	11.0	11.0	47.0
	Cough & cold	38	38.0	38.0	85.0
	Skin problems	15	15.0	15.0	100.0
	Total	100	100.0	100.0	

Cough & cold, muscle pain, cuts & burns, skin problems, diarrhea & constipation are most favored categories for OTC medicine

- **Major sources of information of OTC medicines**

**Statistics**

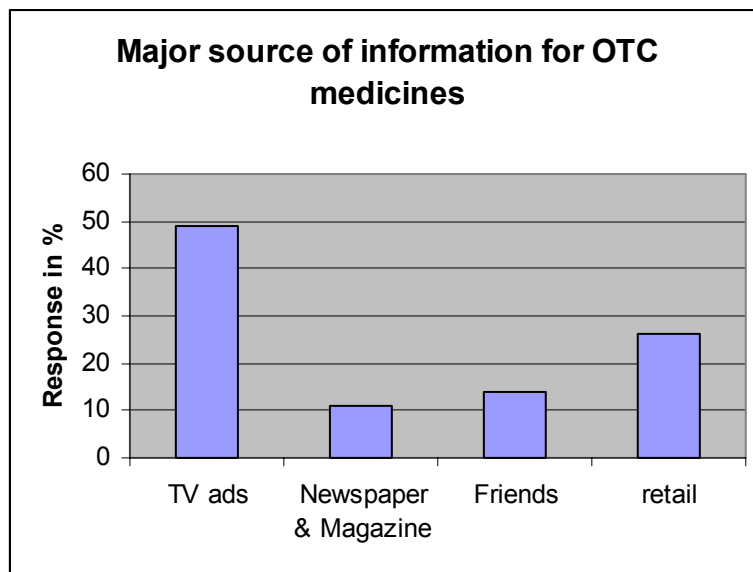
Major source of information

N	Valid	100
	Missing	0

**Major source of information**

	Frequency	Percent	Valid Percent	Cumulative Percent
Valid TV ads	49	49.0	49.0	49.0
Newspaper & Magazine	11	11.0	11.0	60.0
Friends	14	14.0	14.0	74.0
Retail	26	26.0	26.0	100.0
Total	100	100.0	100.0	

• **Major source of information of OTC medicines**



**TV advertisements and Retail are the major source of information for OTC medicines**

**Conclusion**

The study showed a clear willingness among both doctors and consumers to accept more OTC medicines.

When asked for opinions on which categories were suitable for OTC, both groups were receptive to more OTC treatments for Cough & cold, muscle pain, cuts & burns, diarrhea, constipation and skin problems.

Striking a good balance between continued prescription heritage and high consumer familiarity is one of the key factors in a successful Rx-to-OTC switch, as proven by brands such as Benadryl.

Reinforcing strong retail influence and continuous consumer loyalty represents another successful OTC model. Marketers should consider the value of each model on the basis of category of product switch, today’s retail influence and the extent of consumer familiarity with the brand due to present prescription status.

Among various influencers, television followed by retail was the strongest. Innovative integrated media strategy would be one of the major reasons in the early success of OTC switches.