Rx to OTC Switch-Market Analysis

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Introduction

Over-the-counter (OTC) drugs are medicines that may be sold directly to a consumer without a prescription from a healthcare professional, and are commonly used to treat symptoms of common illnesses that may not require the direct supervision of a physician.

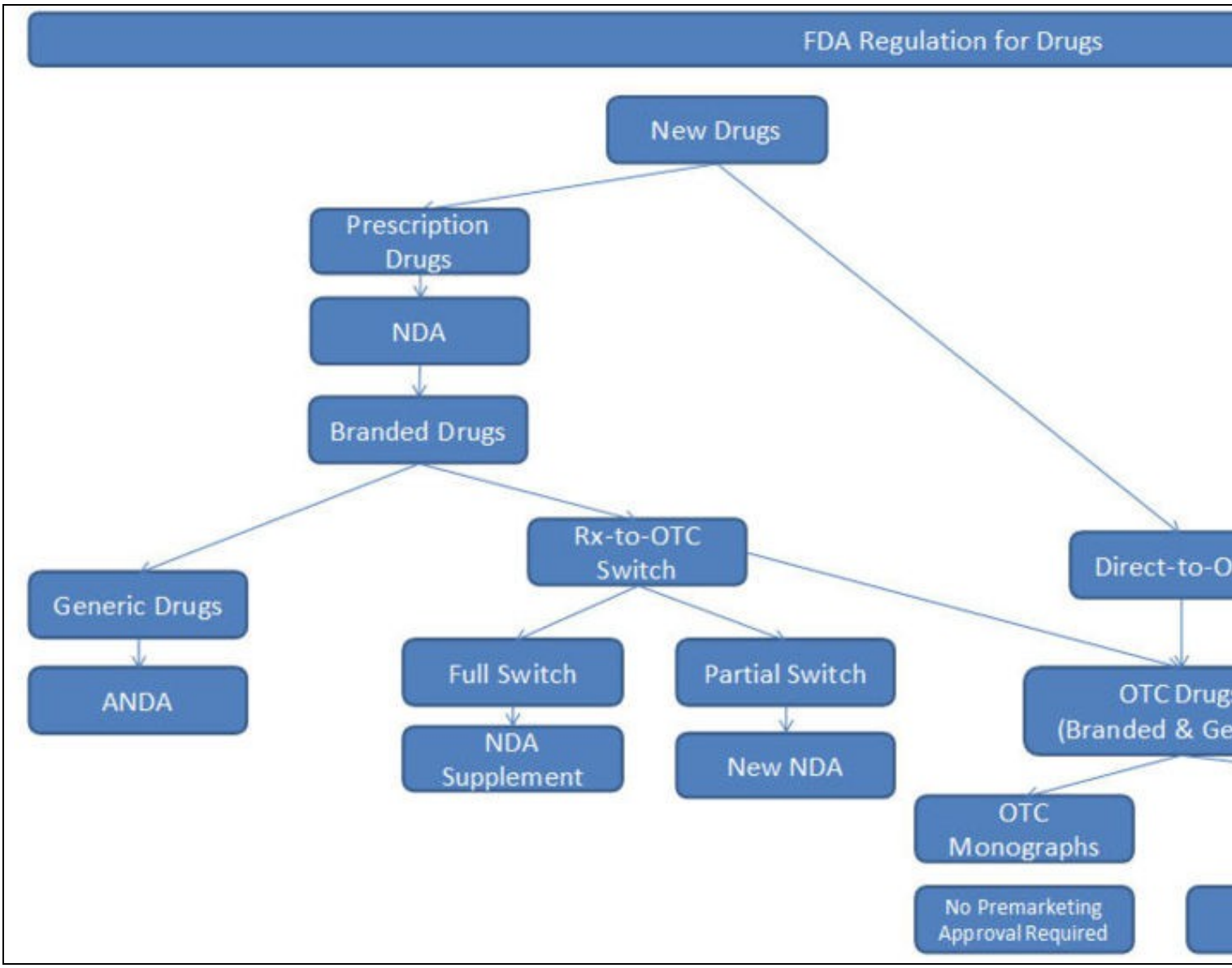
- For a medicine to be granted OTC status, it must have a wide safety margin and be effective, and must bear understandable labeling to ensure proper use
- More than 700 OTC products on the market today use ingredients or dosages, that were available only by prescription, less than 30 years ago
- Rx to OTC switch refers to the transfer of proven prescription drugs (Rx) to non-prescription, over-the-counter (OTC) status. Rx to OTC switch is a data-driven, scientifically rigorous, and highly regulated process that allows consumers to have OTC access to a growing range of medicines

There are two ways in which drugs are commonly switched as approved by FDA in US :

1. The OTC Drug Review
   - Began in 1972
   - Ongoing assessment of the safety and effectiveness of all nonprescription drugs
   - Panels of non-government experts review active ingredients in marketed OTC drug products to determine whether they can be classified as safe and effective
   - About 40 former prescription-only drug ingredients have been switched by this process
2. New drug application (NDA) process
   - Manufacturers submit data to the FDA showing the drug is appropriate for self-administration.
   - The submission includes studies showing that the product's labeling can be read, understood, and followed by the consumer without the guidance of a health care provider
   - Some drugs are approved initially as OTC drugs, but most are first approved for prescription use and later switched to OTC

Rx and OTC Regulation

The FDA process for drug approval is given below



FDA Drug Regulation Process

- NDA - New Drug Application
- ANDA - Abbreviated New Drug Application
- Full NDA- For a new dosage or formulation such as lower strength than Rx version (for a medication currently available by prescription)
- Supplemental NDA ? For a product for which the manufacturer already holds an approved NDA or holds an abbreviated NDA for a closely related product
- Abbreviated NDA ? For products that are identical to an existing prescription product
- The switch to OTC is done in a partial or total way. Most switches are partial, a version of the active ingredient remains available on prescription while a specific indication, strength, or dosage form becomes available through the(new NDA) switch application. On the other hand some switches are full, no prescription version of the active ingredient remains which becomes available through (NDA supplement) switch application.

Source:FDA , Nonprescription Product Therapeutics, Section 1, Chapter 2

Prescription Drugs - Branded

Once a drug has been discovered, the drug manufacturer must test the drug in laboratory and on animals. If it proves effective, the drug is tested in humans to see if it safe and effective. Once it is demonstrated to be safe, the manufacturer sends a **New Drug Application (NDA)** to the FDA to apply for approval. Next come tests in humans to see if the drug is safe and effective when used to treat or diagnose a disease.

New Drug Application (NDA)
The NDA application is the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing in the U.S. The data gathered during the animal studies and human clinical trials of an Investigational New Drug (IND) become part of the NDA. The goals of the NDA are to provide enough information to permit FDA reviewer to reach the following key decisions:

1. Whether the drug is safe and effective in its proposed use(s), and whether the benefits of the drug outweigh the risks.
2. Whether the drug's proposed labeling (package insert) is appropriate, and what it should contain.
3. Whether the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity.

The documentation required in an NDA is supposed to tell the drug's whole story, including what happened during the clinical tests, what the ingredients of the drug are, the results of the animal studies, how the drug behaves in the body, and how it is manufactured, processed and packaged.
NDAs include:

1. The drug's test results
2. Manufacturing information to demonstrate the company can properly manufacture the drug.
3. The company's proposed label for the drug, which should include information about the drug, its uses, and possible risks.

The FDA approves drugs if their benefits outweigh any risks in taking them. Once a drug is approved, its manufacturer can market and then sell it in the U.S. In approving the drug, the FDA also takes into account the proposed name for it. To protect the safety of the public, it is important that the name not be similar to that of another drug product to prevent against mix-ups. FDA's Division of Medication Error Prevention and Analysis reviews the names.

Source:FDA,Pharmacy.About

Prescription Drugs ? Generic

Generic drugs are also known as copycat drugs. They are exact replicas of the branded drugs and typically go by their chemical name-Lipitor's generic is called atorvastatin, for example. They do not have a patent. The manufacturers of generic drugs provide an **abbreviated new drug application (ANDA)** to the FDA to receive approval. Since there is already a drug on the market to help consumers, the approval time for generic drugs is typically longer. The Office of Generic Drugs (OGD), which is a department within the FDA, approves generic drugs.

An Abbreviated New Drug Application (ANDA) is submitted to the FDA when seeking review and approval for a generic drug product. The application is submitted to the FDA's Center for Drug Evaluation and Research, Office of Generic Drugs. If approved, the generic drug may be manufactured and sold in the U.S. market. Generic drug applications are not typically required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness. An applicant submitting an ANDA must scientifically demonstrate that its product is bioequivalent to the previously approved innovator or brand name drug.
Source:Pharmacy.about1, Pharmacy.about2

FDA requires generic drugs to have the same quality and performance as brand name drugs.

1. When a generic drug product is approved, it has met rigorous standards established by the FDA with respect to identity, strength, quality, purity, and potency. However, some variability can and does occur during manufacturing, for both brand name and generic drugs. When a drug, generic or brand name, is mass-produced, very small variations in purity, size, strength, and other parameters are permitted. FDA limits how much variability is acceptable.
2. Generic drugs are required to have the same active ingredient, strength, dosage form, and route of administration as the brand name product. Generic drugs do not need to contain the same inactive ingredients as the brand name product.
3. The generic drug manufacturer must prove its drug is the same as (bioequivalent) the brand name drug. For example, after the patient takes the generic drug, the amount of drug in the bloodstream is measured. If the levels of the drug in the bloodstream are the same as the levels found when the brand name product is used, the generic drug will work the same.
4. Through review of bioequivalence data, FDA ensures that the generic product performs the same as its respective brand name product. This standard applies to all generic drugs, whether immediate or controlled release.
5. All generic manufacturing, packaging, and testing sites must pass the same quality standards as those of brand name drugs, and the generic products must meet the same exacting specifications as any brand name product. In fact, many generic drugs are made in the same manufacturing plants as brand name drug products.

Source: FDA

OTC - Branded & Prescription Drugs

The FDA's **Office of Drug Evaluation IV**, Over-the-Counter Drug Products reviews OTC drugs. A Nonprescription Drug Advisory Committee, comprised of up to 14 independent experts selected by the FDA commissioner, assists the FDA in reviewing issues surrounding OTC drugs, including switching drugs from prescription to non-prescription status.

Instead of reviewing the labels and ingredients of all 300,000 OTC drugs now being marketed, the FDA focuses on about 80 different therapeutic classes of drugs, such as analgesics, antacids, antimicrobial, antiperspirants, dental and cough/cold medicines.

The FDA publishes an **OTC drug monograph** for each category of drug in the Federal Register. Drug monographs serve as a cook book, or list of recipes, that include acceptable ingredients, formulations, dosages and labeling for each category of drug.The monograph explains the types of ingredients that may be used to treat certain diseases or conditions without a prescription, the appropriate dose and instructions for use, and labeling.

Once a monograph is adopted, companies may develop and market an OTC product without pre-approval from the FDA. Products that do not adhere to the monograph must be reviewed through FDA?s **New Drug Application** process.A drug company can also petition the FDA to deviate from the ingredient or labeling requirements of an OTC monograph.

1. Over-the-counter (OTC) drugs are drugs that the FDA has decided are safe and appropriate for use without the supervision of a health care professional and can be purchased without a prescription.
2. Products conforming to a monograph may be marketed without further FDA clearance, while those that do not must undergo separate review and approval through the "New Drug Approval System".
3. OTC products that meet a monograph's requirements may be marketed without FDA review. OTC products that do not fit under an existing monograph must be approved under an application like the **applications for prescription products**.

Source:Pharmacy.About1,Pharmacy.About2

Rx to OTC Switch ? Regulatory Process

There are 2 regulatory pathways for getting approval for OTC drugs (Rx to OTC switch and Direct to OTC)

1. OTC New Drug Application (NDA)
2. OTC Drug Monograph

Rx-to-OTC switches

The applications differ based on whether the manufacturer wants to switch to OTC completely or partially.

1. Full switch (NDA supplement)
2. Partial switch (new NDA)

Source:FDA

Direct-to-OTC

1. OTC Monographs
2. OTC NDA

Source:OTC Regulation in Different Countries

FDA Applications

1. An efficacy supplement should be submitted to an approved NDA for a prescription product if the sponsor plans to switch the drug product covered under the NDA to OTC marketing status in its entirety without a change in the previously approved dosage form or route of administration.
2. An NDA 505(b)(1) should be submitted if the sponsor is proposing to convert some but not all of the approved prescription indications to OTC marketing status.
3. An original NDA (505)(b)(1) or 505(b)(2) needs to be submitted if the sponsor plans to market either a new product OTC whose active substance, indication, or dosage form has never previously been marketed OTC.

OTC drug review

The OTC drug review was established to evaluate the safety and effectiveness of OTC drug products marketed in the United States before May 11, 1972. It is a three-phase public rulemaking process (each phase requiring a Federal Register publication) resulting in the establishment of standards (monographs or non-monographs) for an OTC therapeutic drug category.

First phase

The first phase was accomplished by advisory review panels. The panels were charged with reviewing the ingredients in nonprescription drug products to determine whether these ingredients could be generally recognized as safe and effective for use in self-treatment. They were also charged with reviewing claims and recommending appropriate labeling, including therapeutic indications, dosage instructions, and warnings about side effects and preventing misuse.
According to the terms of the review, the panels classified ingredients in three categories as follows:

1. Category I: generally recognized as safe and effective for the claimed therapeutic indication;
2. Category II: not generally recognized as safe and effective or unacceptable indications;
3. Category III: insufficient data available to permit final classification

Second phase

The second phase of the OTC drug review was the agency?s review of ingredients in each class of drugs, based on the panel?s findings, on public comment, and on new data that may have become available. The agency, in turn, publishes its conclusions in the Federal Register in the form of a tentative final monograph. After publication of the tentative final monograph, a period of time is allotted for objections to the agency?s proposal or for requests to be submitted for a hearing before the Commissioner of FDA.

Third phase

The publication of final regulations in the form of drug monographs is the third and last phase of the review process. The monographs establish conditions under which certain OTC drug products are generally recognized as safe and effective.

Clinical Trials : Rx-to-OTC

Clinical trials are not a compulsory requirement for Rx-to-OTC switches, but most switch applications include new clinical trial data for the non-prescription indication and almost all the switch applications include label comprehension studies and/or actual use studies to demonstrate that the medicine can be used safely and effectively in the consumer target population. Additional standard efficacy and safety clinical trials are to prove the drug can be used safely in an OTC setting.

FDA?s Center for Drug Evaluation and Research (CDER) defines OTC drug actual use study as ?a controlled experiment in which a prescription drug or unapproved new drug is used by subjects under OTC-like conditions.? OTC studies are intended to support a significant change in labelling for the drug. These studies are considered the most important in assessing a drug?s appropriateness for a switch. The main Objectives of an Rx-to OTC study fall into four main categories:

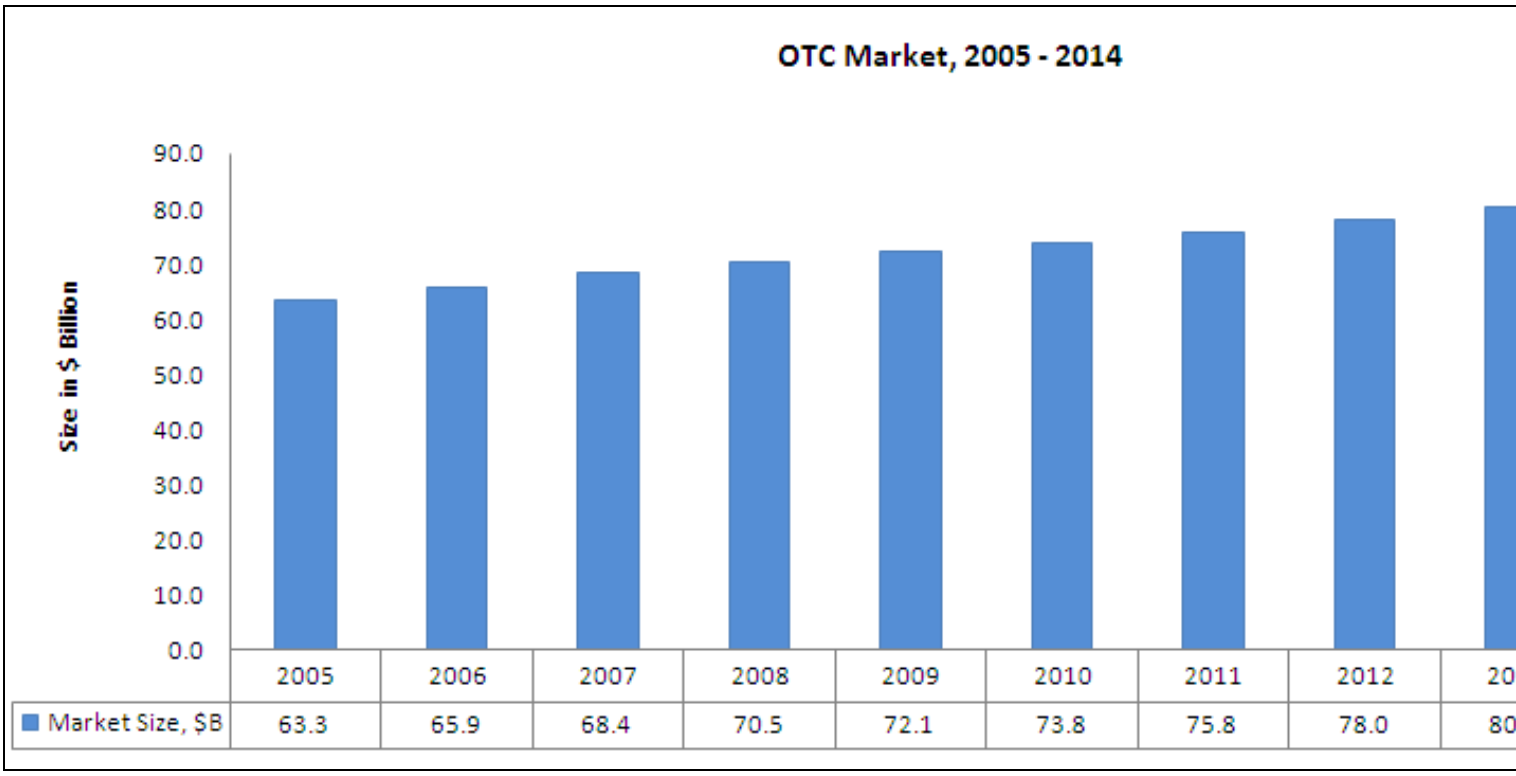
1. Safety (prescription safety demonstrated by previous trials)
2. Comprehension (demonstrated by label comprehension studies)
3. Self-selection and de-selection
4. Compliance as the core issue

If the drug has a good safety profile, shown by the studies done to support its marketing as a prescription drug, and if the drug meets the specific criteria for switching which includes ability of selection or de-selection by consumer, there is relatively good chance that FDA will approve it for OTC use.

Source:FDA, Compliance Online

Market Overview

OTC Market



Source:Kalorama Information

Time Period	CAGR
2005-2009	3.3%
2009-2014	2.7%
2005-2014	3.0%

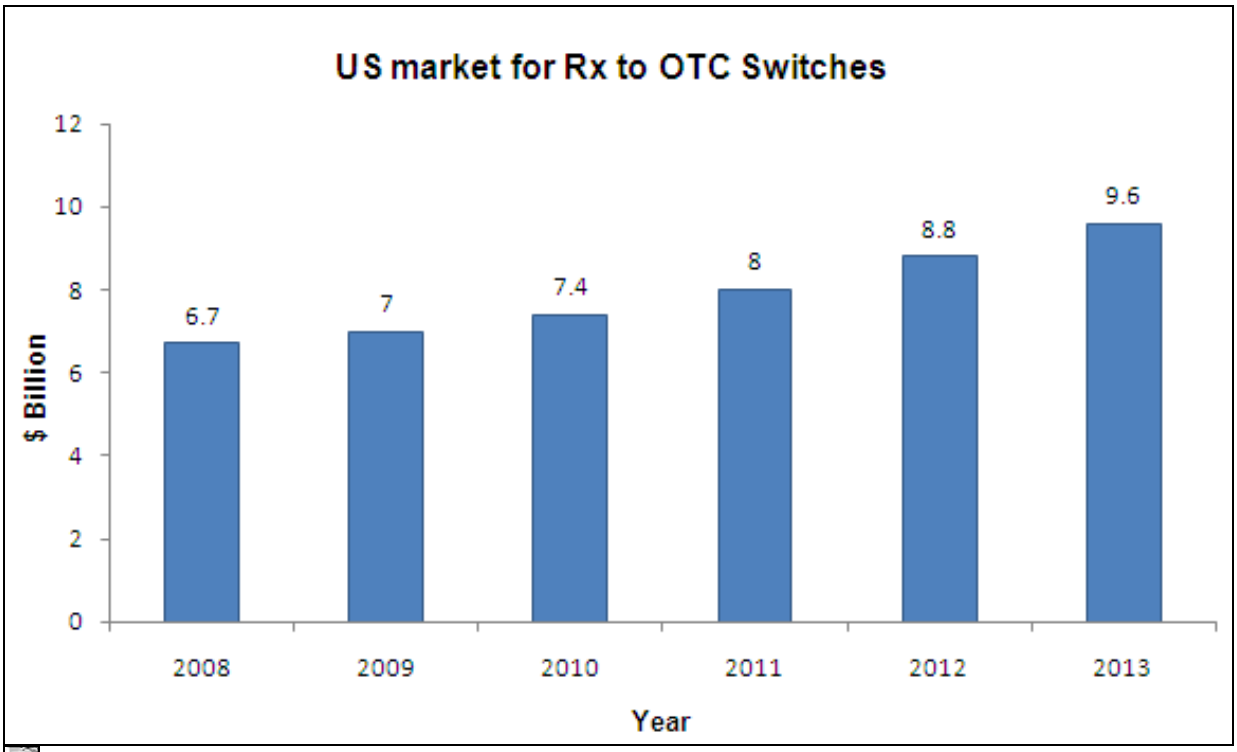
Rx vs. OTC Market

Total Pharmaceutical Market by Country, 2009 ($B)

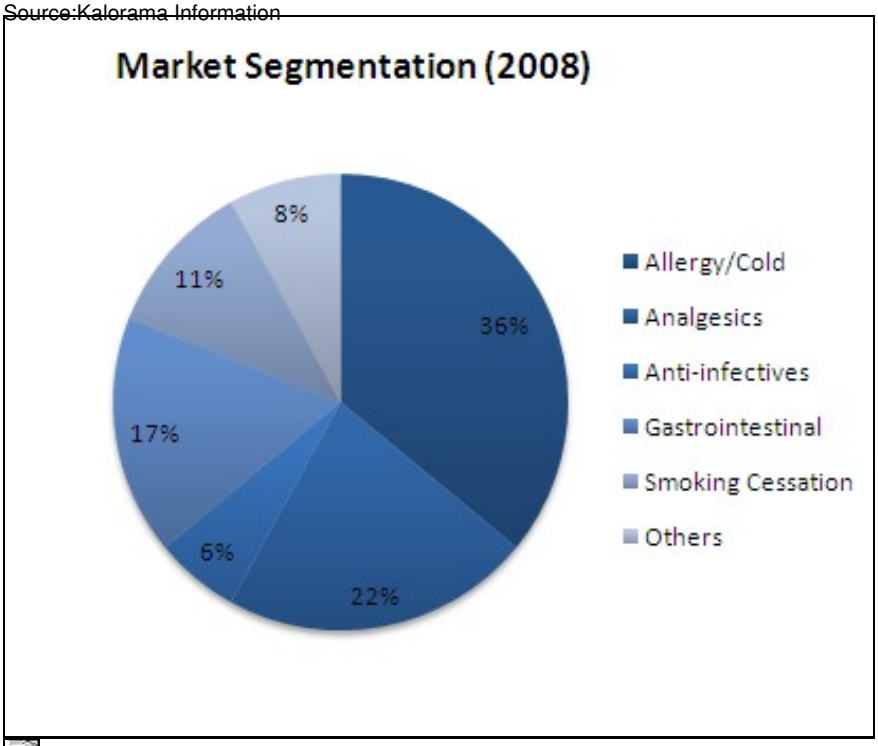
Country	Rx Market	OTC Market	Total Pharma Market	OTC as % of Total Pharma Market
United States	214	18	232	**7.8**
Japan	56	11	67	**16.4**
Germany	35	5	40	**12.5**
France	32	4	36	**11.1**
China	16	5	21	**23.1**
United Kingdom	17	3	20	**15.0**
Russia	13	3	16	**18.8**
Brazil	10	2	12	**16.7**
Mexico	9	2	11	**18.1**
India	6	3	9	**33.3**

Source: Kalorama Information

Rx to OTC Switches



Source:Kalorama Information



Source:Kalorama Information

- CAGR for 2008-2013 is **9.4%**

Major OTC Players

Supplier	Segments of Major Participation					
	Allergy/Cold	Analgesics	Anti-infectives	Gastrointestinal	Smoking Cessation	Othe
Bayer Consumer	✓	✓				
Boehringer Ingelheim				✓		
GlaxoSmithKline Consumer	✓			✓	✓	
McNeil Consumer/ McNeil-PPC	✓	✓	✓	✓		
J&J/Merck Consumer Products				✓		
Novartis Consumer	✓		✓		✓	
Procter & Gamble Co.	✓			✓		
Schering-Plough	✓		✓	✓		
Wyeth Consumer	✓	✓		✓		

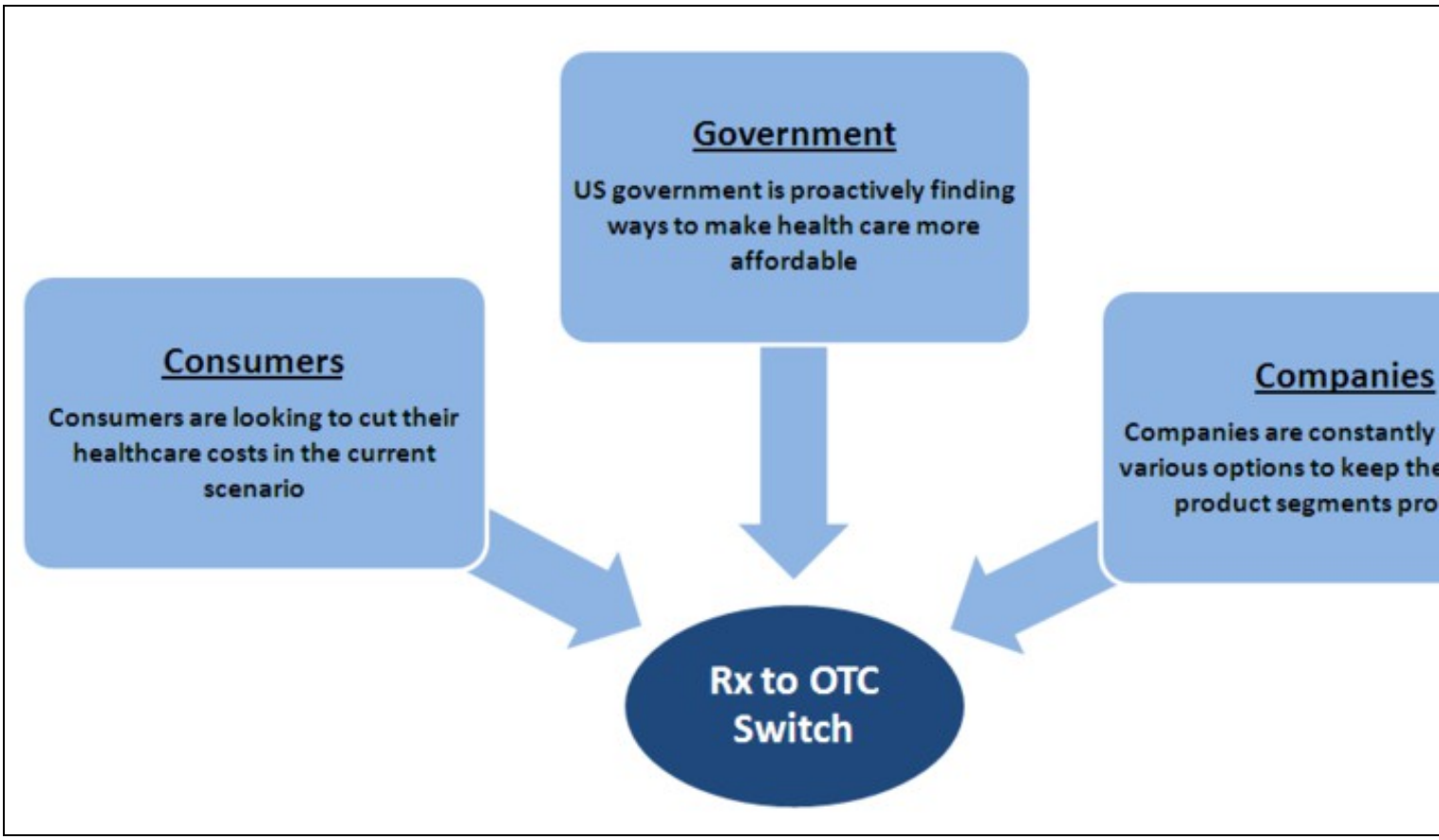
Source:Company Websites

Sales Data for selected Rx to OTC Switches, USA

S.No	Switched Drug	Manufacturer/Marketer	Drug Category	Switch Year	First 12-Month Sales (in $M)
1	Alli	Glaxo SmithKline Consumer Healthcare	Weight Loss Aid	2007	80
2	MiraLax	Schering-Plough Healthcare	Gastrointestinal	2006	40
3	Prilosec OTC	Procter & Gamble	Gastrointestinal	2003	130
4	Claritin	Schering-Plough Healthcare	Allergy	2002	380
5	Nicoderm CQ	Glaxo SmithKline Consumer Healthcare	Smoking Cessation	1996	160
6	Nicorette	Glaxo SmithKline Consumer Healthcare	Smoking Cessation	1996	195
7	Rogaine	McNeil Consumer Healthcare	Hair Loss	1996	180
8	Pepcid AC	Johnson & Johnson- Merck Consumer Pharmaceuticals Co.	Gastrointestinal	1995	200
9	Zantac 75	Boehringer Ingelheim Consumer Healthcare Products	Gastrointestinal	1995	140
10	Aleve	Bayer Consumer Care	Analgesic	1994	110

Source:Company Websites, Press Releases and Journals

Factors Affecting Rx to OTC Switch



Trends in Rx to OTC Switches

Rx-to-OTC Switches Since 2000

S.No	Ingredient	Product Category	Date of OTC Approval	Product Examples	Company
1	ibuprofen (NDA)	migraine	25/02/2000	Motrin Migraine Pain	McNeil Consumer Healthcare
2	docosanol (NDA)	cold sore/fever blister	25/07/2000	Abreva Cream	Avanir Pharmaceuticals
3	famotidine, calcium carbonate, magnesium hydroxide (NDA)	heartburn, acid indigestion	17/10/2000	Pepcid Complete	J&J/Merck
4	butenafine hydrochloride (NDA)	athlete's foot, jock itch, ringworm	7/12/2001	Lotrimin Ultra	Schering-Plough
5	ibuprofen, pseudoephedrine HCl, suspension for pediatric use (NDA)	analgesic/decongestant	18/04/2002	Children?s Advil Cold	Wyeth
6	guaifenesin extended-release tablet (NDA)	expectorant	12/7/2002	Mucinex	Adams Respiratory Therapeutics
7	nicotine polacrilex troche/lozenge (NDA)	smoking cessation	31/10/2002	Commit	GlaxoSmithKline
8	loratadine (NDA)	antihistamine	27/11/2002	Claritin Tablets, Claritin RediTabs, Claritin Syrup	Schering-Plough
9	loratadine, pseudoephededrine sulfate (NDA)	antihistamine/ decongestant	27/11/2002	Claritin-D 12 Hour Extended Release Tablets,	Schering-Plough
10	omeprazole magnesium	acid reducer to treat frequent heartburn	20/06/2003	Prilosec OTC	Procter & Gamble
11	loratadine (NDA)	hives relief	15/11/2003	Claritin hives relief	Schering-Plough
	diphenhydramine citrate & ibuprofen (NDA); diphenhydramine HCl & ibuprofen	analgesic sleep-aid	21/12/2005	Advil PM	Wyeth

	potassium (NDA)				
12	ecamsule (combined with avobenzone and octocrylene (NDA)	sunscreen	21/07/2006	Anthelios SX	L?Oreal
13	levonorgestrel (NDA)	contraceptive	24/08/2006	Plan B	Duramed
	polyethylene glycol 3350 (NDA)	laxative	6/10/2006	MiraLAX	Schering-Plough
14	ketotifen (NDA)	antihistamine eye drops	19/10/2006	Zaditor	Novartis
15	orlistat (NDA)	weight loss aid	7/2/2007	alli	GlaxoSmithKline
16	cetirizine HCl & pseudoephedrine HCl (NDA)	antihistamine/ decongestant	9/11/2007	Zyrtec-D	McNeil
17	cetirizine HCl (NDA)	antihistamine, hives relief	16/11/2007	Zyrtec	McNeil
18	lansoprazole (NDA)	acid reducer to treat frequent heartburn	18/05/2009	Prevacid 24 HR	Novartis
19	levonorgestrel (NDA)	contraceptive	10/7/2009	Plan B One Step	Duramed
20	omeprazole and sodium bicarbonate (NDA)	acid reducer to treat frequent heartburn	1/12/2009	Zegerid OTC	Schering-Plough

- Blue highlighted drugs are patent-protected
- Purple highlighted drugs are under FDA exclusivity period

Rx to OTC Switches before patent expiry

S.No	Product Examples	Company	Date of OTC Approval	Patent Expiry	FDA Exclusivity	Patent Number
1	Abreva Cream	Avanir Pharmaceuticals	25/07/2000	28/04/2014	--	4874794
2	Pepcid Complete	J&J/Merck	17/10/2000	15/10/2000	--	4283408
3	Mucinex	Adams Respiratory Therapeutics	12/7/2002	28/04/2020	--	6372252
4	Commit	GlaxoSmithKline	31/10/2002	21/08/2010	--	5110605
5	Prilosec OTC	Procter & Gamble	20/06/2003	15/11/2019	--	5690960, 5753265, 5817338, 5900424, 6403616, 6428810
6	Claritin hives relief	Schering-Plough	15/11/2003	19/06/2002	--	4282233
7	Anthelios SX	L?Oreal	21/07/2006	24/12/2013	--	5587150
8	Plan B	Duramed	24/08/2006	--	24/08/2009	--
9	MiraLAX	Schering-Plough	6/10/2006	--	6/10/2009	--
10	alli	GlaxoSmithKline	7/2/2007	6/1/2018	7/2/2010	6004996
11	Zyrtec-D	McNeil	9/11/2007	10/6/2022	--	6469009, 6489329, 7014867, 7226614
12	Zyrtec	McNeil	16/11/2007	2/7/2018	--	6455533
13	Prevacid 24 HR	Novartis	18/05/2009	--	18/05/2012	--
14	Plan B One Step	Duramed	10/7/2009	--	10/7/2012	--
15	Zegerid OTC	Schering-Plough	1/12/2009	15/07/2016	--	6489346, 6645988, 6699885, 7399772

- Purple highlighted drugs are under FDA exclusivity period

Trend Analysis

1. 11 out of 22 recent drugs (**50%**) which switched from Rx to OTC were **patent protected**
2. 4 out of 22 recent drugs (**18.2%**) which switched from Rx to OTC were under **FDA exclusivity period**
3. 13 out of 22 recent drugs (**59%**) were switched from Rx to OTC before their patent or FDA exclusivity expiry. 2 drugs switched after the expiry of patents
4. 6 out of these 13 drugs made a switch more than 10 years before expiry

5. 5 out of these 13 drugs made a switch between 3 to 10 years before expiry

Potential Drugs for Rx-to-OTC Switch

S.No	Drug	Patent Expiry Date	Expected Switch Year	US Patent Numbers
1	Allegra	14/3/2017	2012	5578610, 6037353, 6187791, 6399632, 7138524
2	Clarinex	1/12/2018	>2013	6514520, 7211582, 7214683, 7214684
3	Crestor	17/6/2022	>2014	6858618, 6316460, 7030152, RE37314
4	Lescol	12/6/2012	>2014	5356896, 5354772,
5	Lipitor	8/1/2017	>2014	5969156, 4681893, 5273995, 5686104, 5969156, 6126971, RE40667
6	Pravachol	22/10/2014	>2014	5622985
7	TriCor	21/2/2023	>2014	7276249, 5145684, 6277405, 6375986 , 6652881, 7037529, 7041319, 7320802
8	Vytorin	25/4/2017	>2014	RE37721, 5846966,
9	Zetia	25/7/2022	>2014	7030106, 5846966, 7612058, RE37721
10	AcipHex	8/5/2013	2013	5045552
11	Nexium	25/11/2018	>2014	7411070, 5690960, 5714504, 5877192, 5900424, 6147103, 6166213, 6191148, 6369085, 6428810, 6875872
12	Protonix	30/3/2025	2010	7553498, 4758579, 7544370, 7550153
13	Zofran	7/12/2026	>2014	7544370, 4758579, 7550153, 7553498
14	Propecia	5/11/2013	2011	5571817, 5547957, 5886184
15	Imitrex	10/3/2014	>2010	5554639, 5307953, 5705520
16	Actonel	10/12/2018	>2014	6165513, 5583122, 6096342
17	Boniva	2/9/2014	>2014	5662918, 4927814
18	Fosamax	17/1/2019	>2014	6225294, 5462932, 5994329, 6015801
19	Evista	10/3/2017	>2014	6894064, 6797719, 6458811, 5393763, 5457117, 5478847, 5811120, 5972383, 6906086, RE38968, RE39049, RE39050
20	Detrol	11/5/2020	>2014	5382600, 6630162, 6770295, 6911217
21	Ditropan	22/11/2015	>2014	5674895, 5840754, 1 5912268, 6262115, 6919092
22	Cialis	26/4/2020	>2014	7182958, 5859006, 6140329, 6821975, 6943166
23	Levitra	31/10/2018	>2014	6362178, 7696206
24	Viagra	22/10/2019	>2014	6469012, 5250534

US Market Survey - Physicians Preferences and Insights

Objectives of Survey

- To find Physician preferences for OTC drugs in comparison to prescription drugs
- To find insights on OTC drugs market and usage
- To understand the effectiveness of different sources of marketing

Research Methodology

The research instrument used was a questionnaire survey administered to collect empirical data. The physician responses were kept confidential to encourage openness and disclosure. The respondents rated the questions on Yes or No, ticked the relevant choices from the options available and ranked the options on a numerical scale. All the responses were coded using a binary system logic and analysis was done to derive insights there after.

Sample Size and Screening Criteria

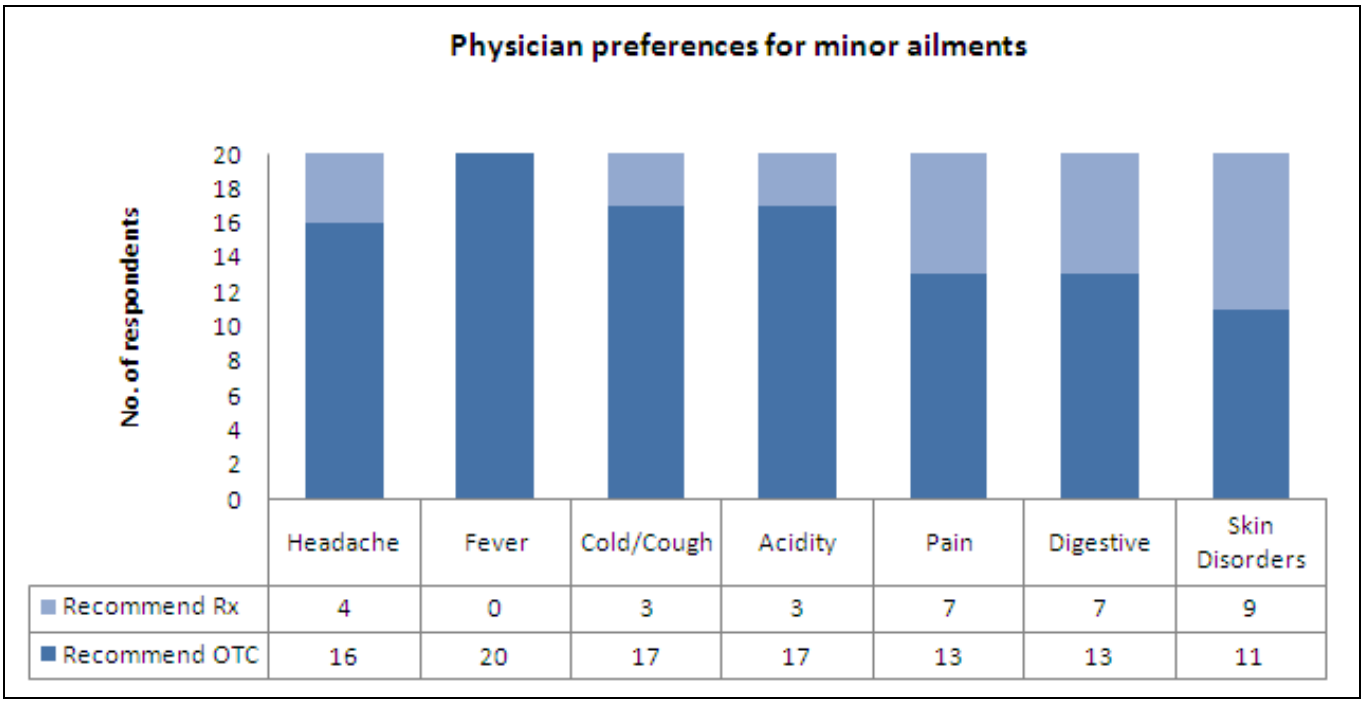
Gender	Sample Size
Male	18

Female	2
Total Physicians	**20**

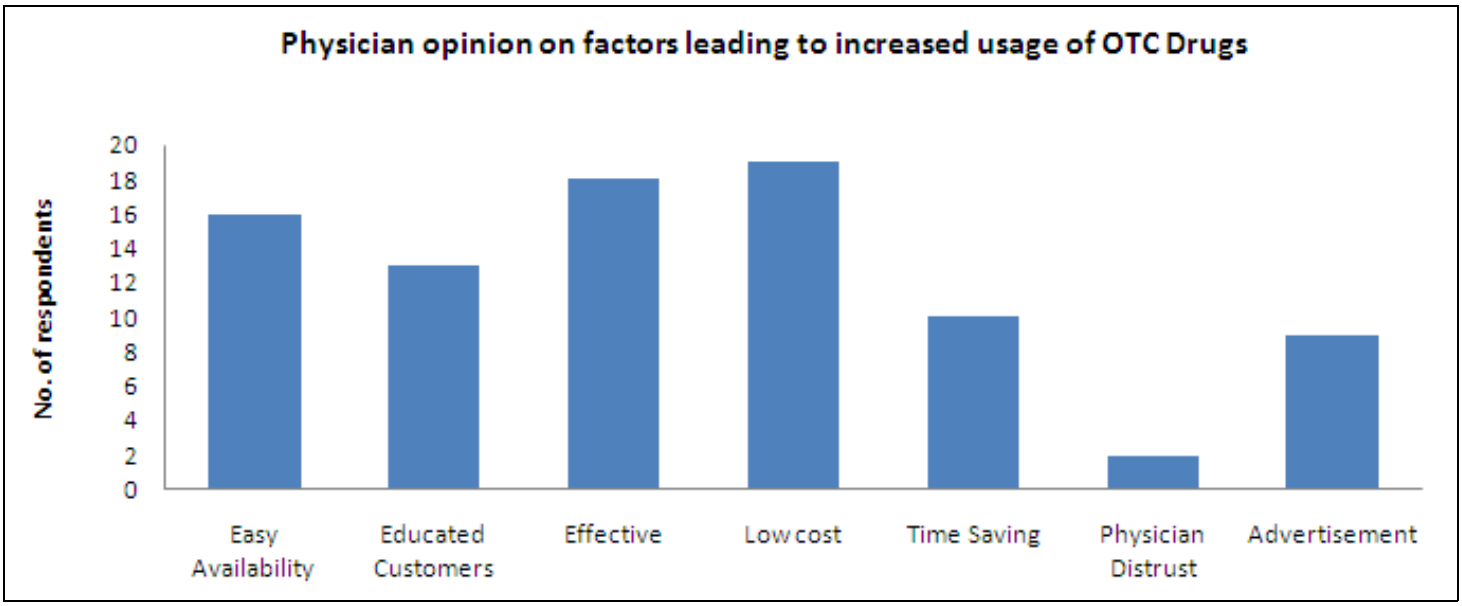
Screening Criteria	
Primary Medical Specialty	General Physician/Family Practice
No. of years in practice	10
No. of patients consulting per month	150

Survey Results

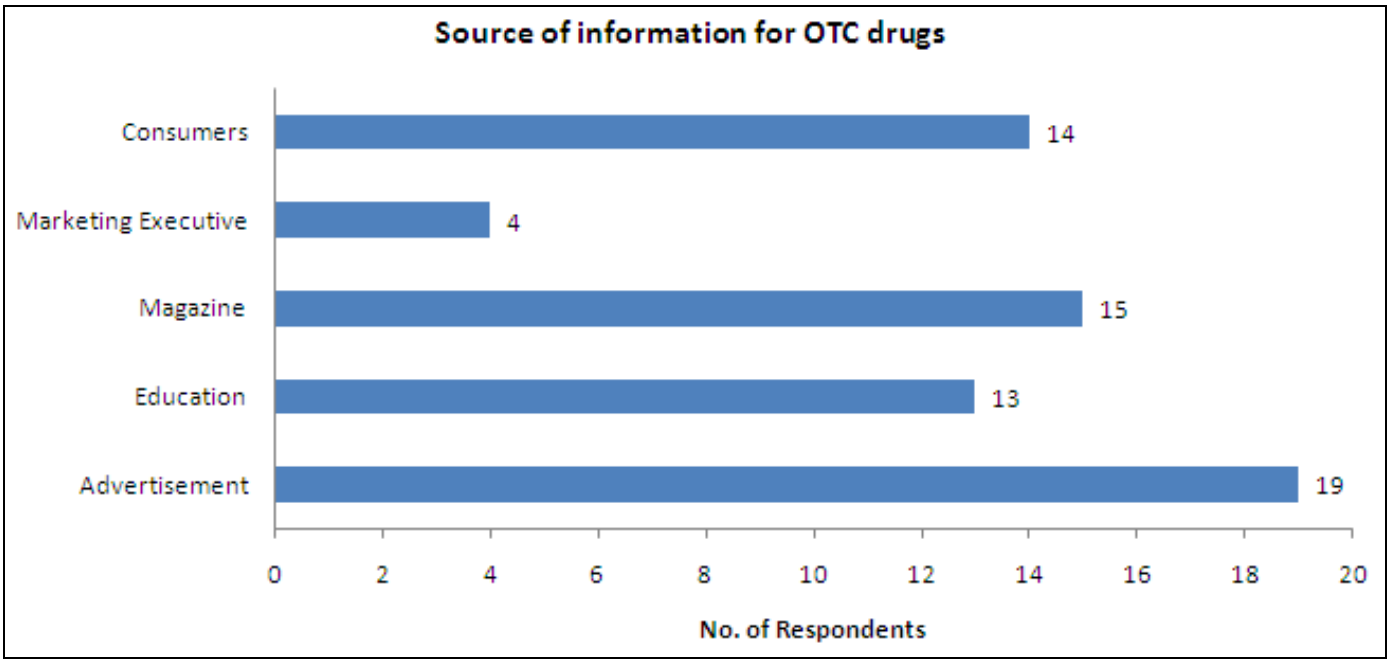
- All the respondents would recommend an OTC drug for fever
- About 95% of the doctors feel that the usage of OTC drugs has increased in the past five years
- About 85% of them would do so for other minor ailments like cold/cough and acidity



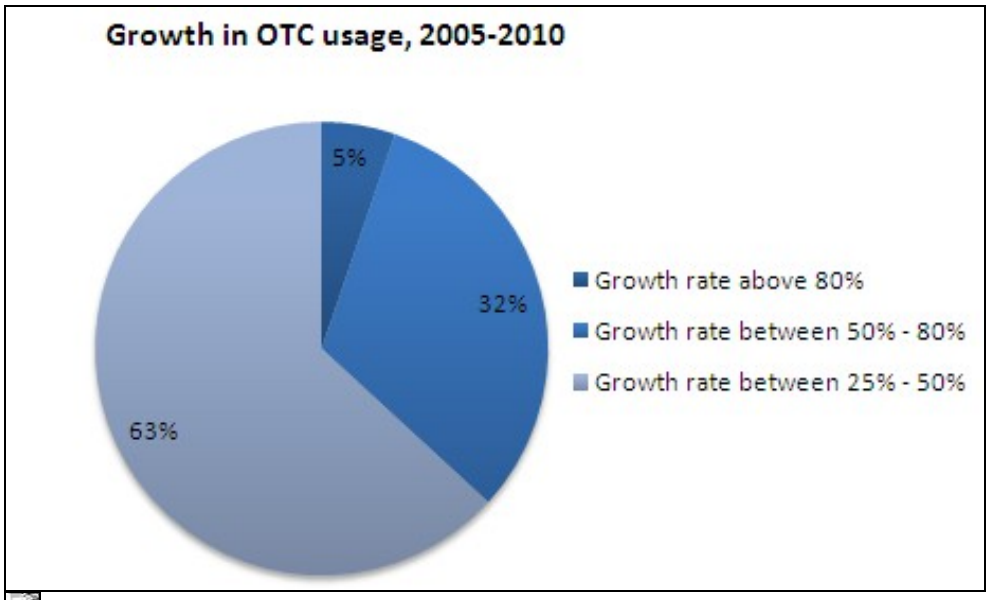
- Low cost, effective and easy availability are selected as the major factors that resulted in increased usage of OTC drugs
- All the respondents feel it is important to prescribe a drug that minimizes patients' out-of-pocket costs, while choosing between equally effective and safe medications

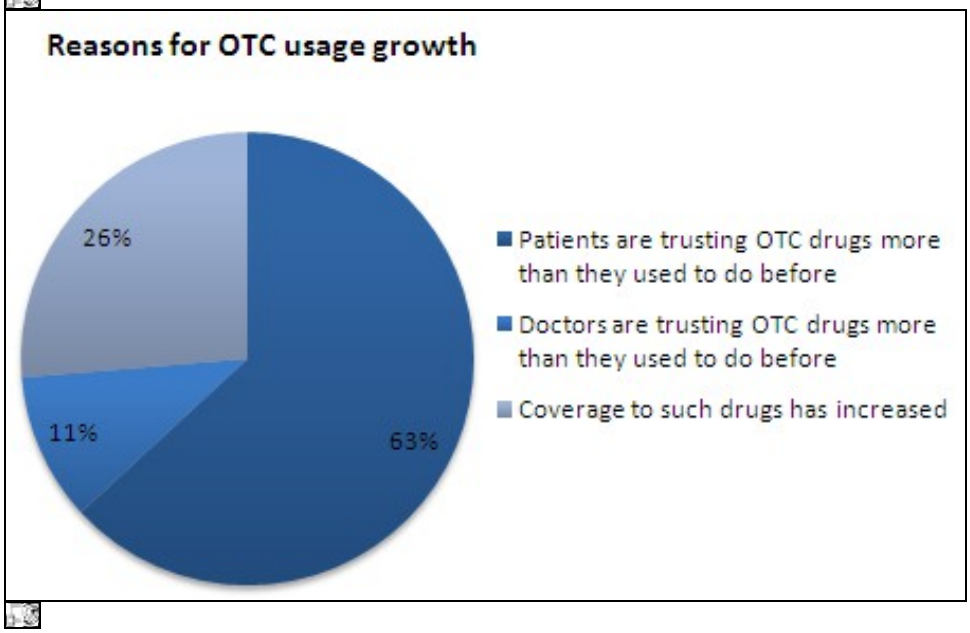


- Advertisement is the major source of information on OTC drugs for most of the respondents
- Only 30% of respondents replied in positive when asked about permitting marketing executives to market OTC products through them

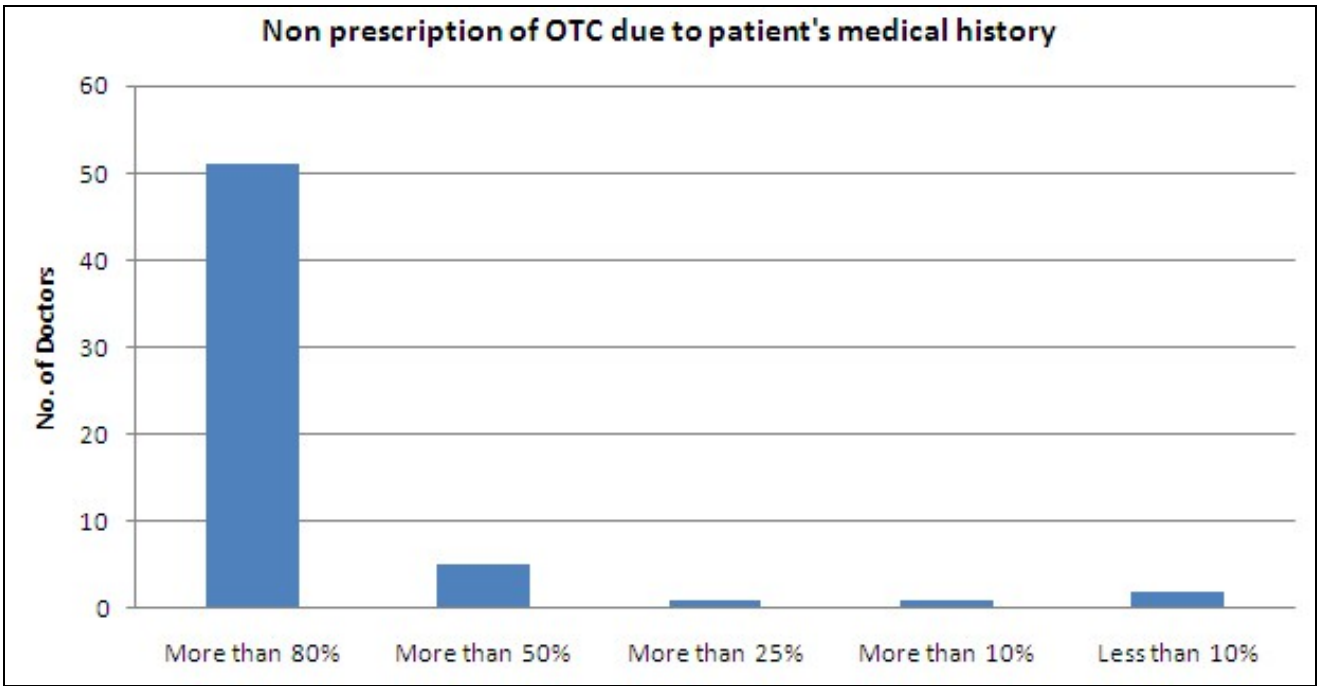


- About 63% of the respondents reported the growth rate of OTC usage during 2005-2010 between 25% - 50% and equal percentage of respondents stated that patients are trusting OTC drugs more than they used to do before as the prime reason for the growth

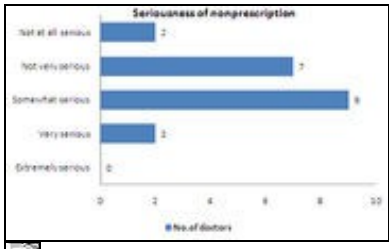




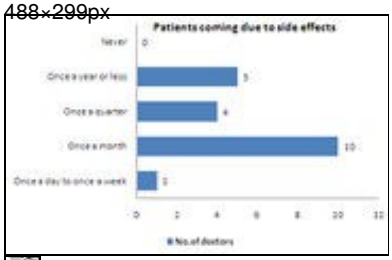
• Less than 50% of the patients are not prescribed OTC due to their medical history



- The case of patients coming to the doctor due to side effects from OTC drugs happens once a month
- About 45% of the respondents feel that non-prescription of drugs is not a serious problem



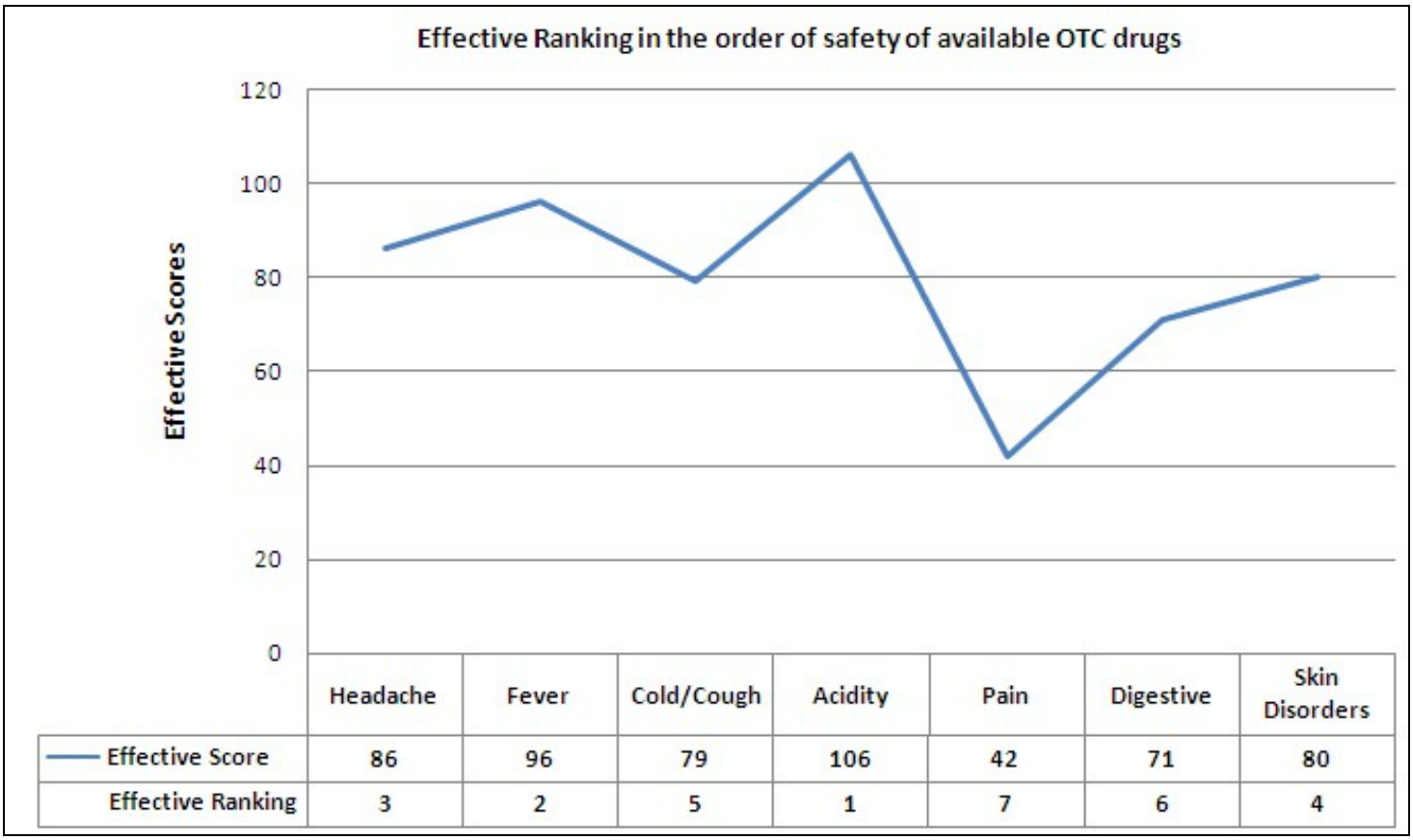
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- 85% of the doctors feel that the information on the label of OTC drugs is sufficient for the patients, in order to take OTC medicines
- 50% of the doctors feel that more OTC drugs should be included under Medicare/insurance coverage

The effective ranking of the ailments in the order of safety of available OTC drugs is as follows:



To see the calculation of the effective scores and effective ranking, click on this link

Indian Market Survey - Physicians Preferences and Insights

Objectives of the Survey

The reason for carrying out this research is to determine the scope of potential switch of prescription drugs to over the counter drugs in the Indian pharma industry. The study is particularly focused at the scope of making statins(a drug for reducing cholesterol level) available over-the-counter. The study aims to understand how successful a switch would be, and if it is safe for such drugs to be made available without prescription. The study also aims at determining the marketing pattern of over the counter drugs, and how it can be improved in future.

The objectives for the survey are :

- To understand the effectiveness of OTC drug marketing campaigns in India
- To understand the source of information for the OTC drugs among doctors
- To explore the potential of switch from Rx to OTC drugs
- To gauge the current prescription pattern of statins in India
- To identify if statins can be switched to OTC

Research Methodology

The research instrument used was a questionnaire survey administered to collect empirical data. The physician responses were kept confidential to encourage openness and disclosure. The respondents rated the questions on Yes or No, ticked the relevant choices from the options available and ranked the options on a numerical scale. All the responses were coded using a binary system logic and analysis was done to derive insights there after.

Sample Size and Screening Criteria

Screening Criteria

Screening Criteria	
Medical Specialty	General Physician, Consulting Physician, Gynaecologist, Dermatologist, Cardiologist, Pediatrician
No. of years in practice	10
No. of patients consulting per month	150

Sample Size

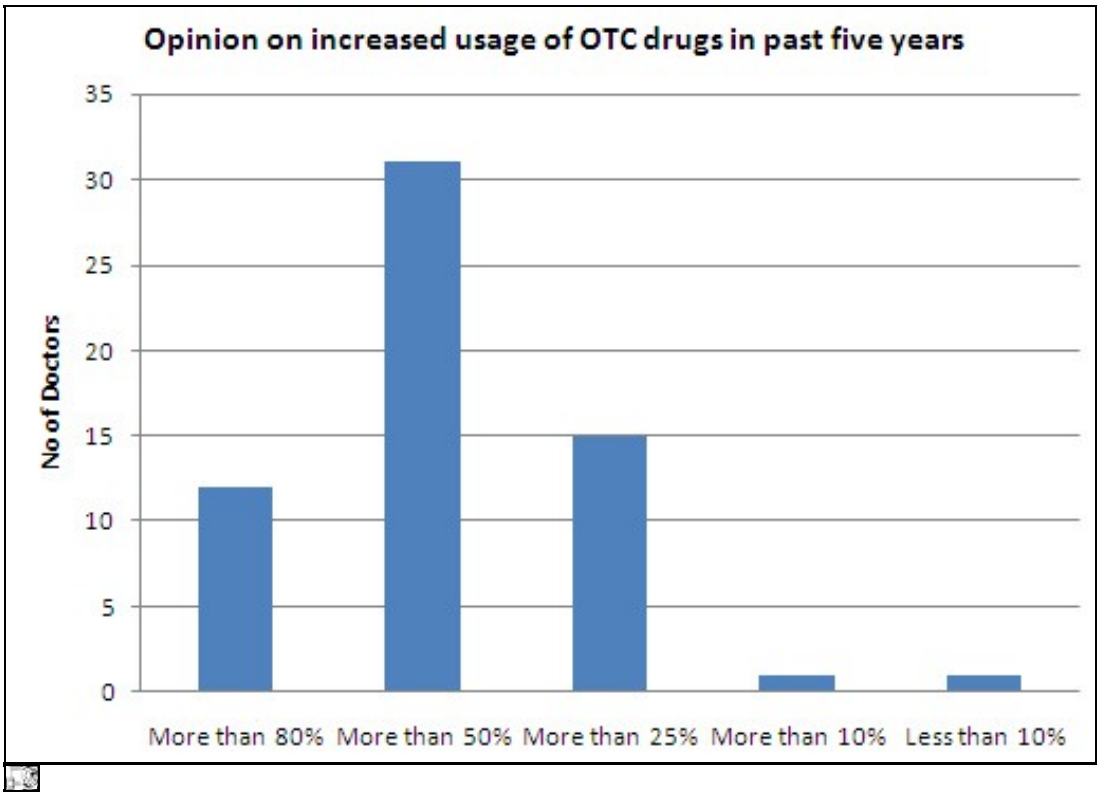
Gender	Sample Size

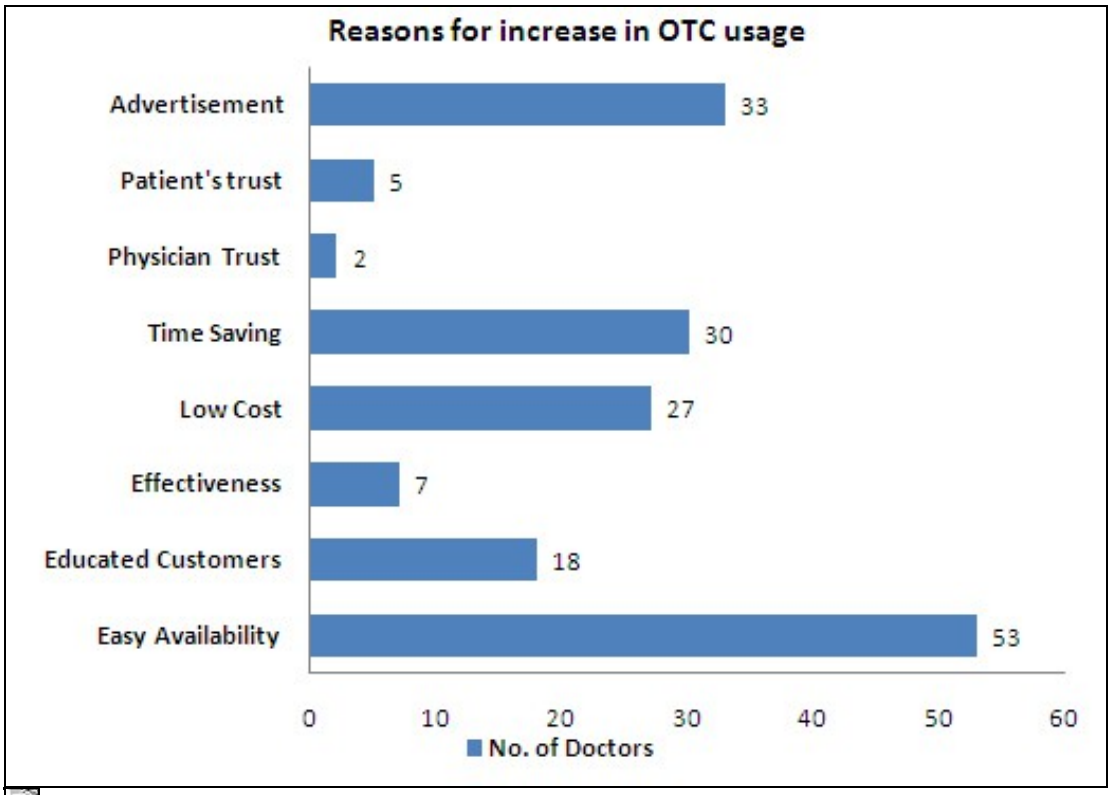
Male	44
Female	16
Total Physicians	**60**

Medical Specialty-wise Breakup	
General Physician	17
Consulting Physician	9
Gynecologist	9
Dermatologist	4
Cardiologist	12
Pediatrician	6
Geographywise Breakup	
Mumbai	15
Hyderabad	15
Delhi NCR	14
Bangalore	16

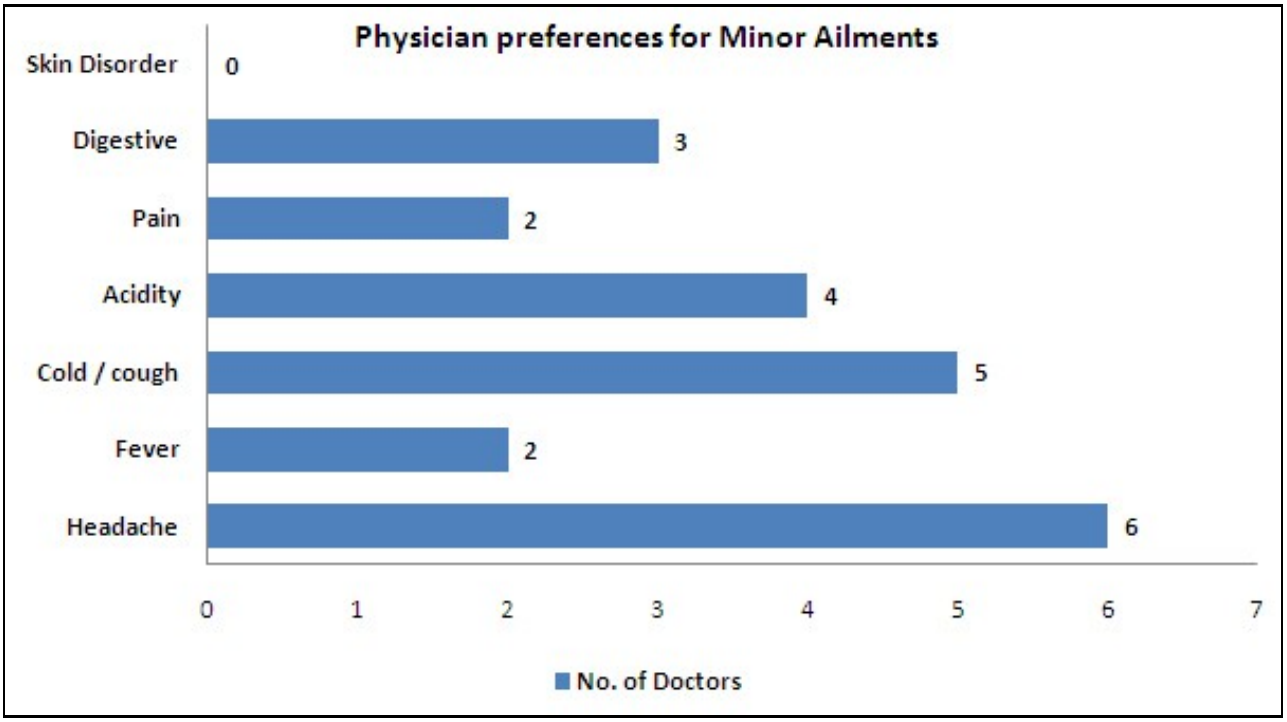
Survey Results

- 97% of the Indian doctors feel that the usage of OTC drugs has increased in the past 5 years
- Indian doctors feel that the usage of OTC drugs has increased by more than 50% in the past 5 years
- Ease in the availability of OTC drugs, Advertisements and Saving time are the major reasons for increase in the usage of OTC drugs

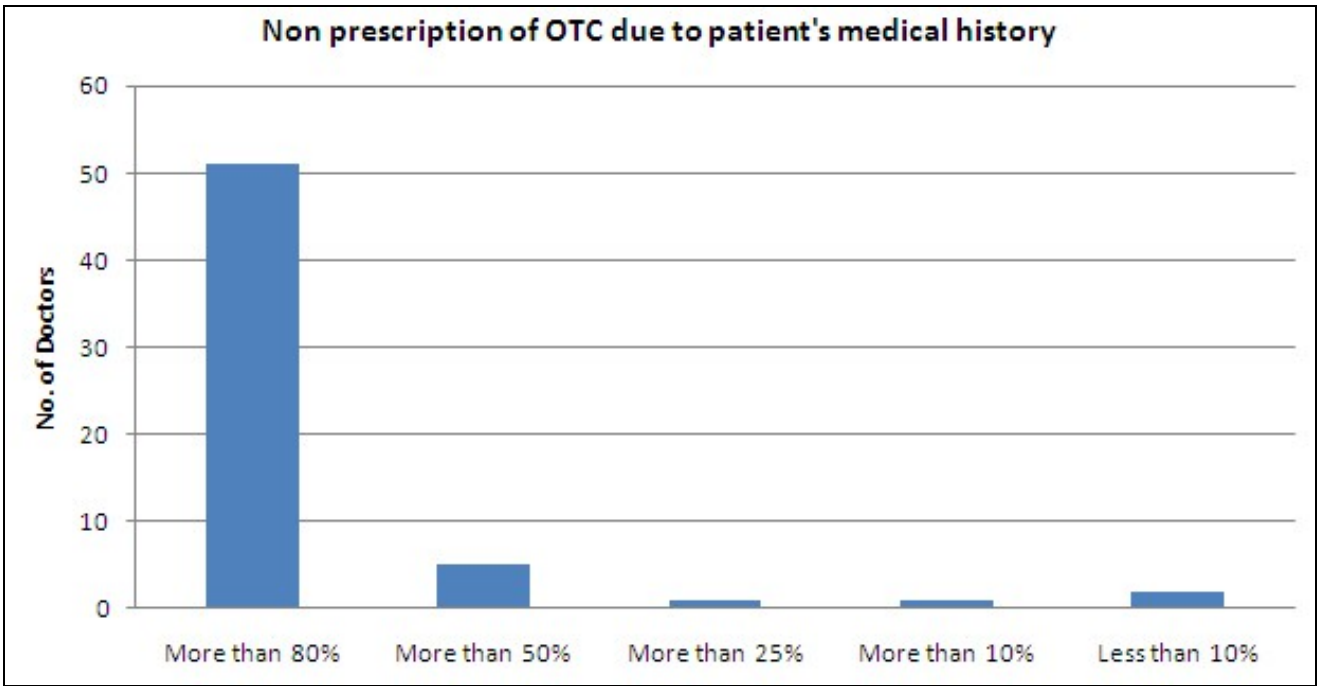




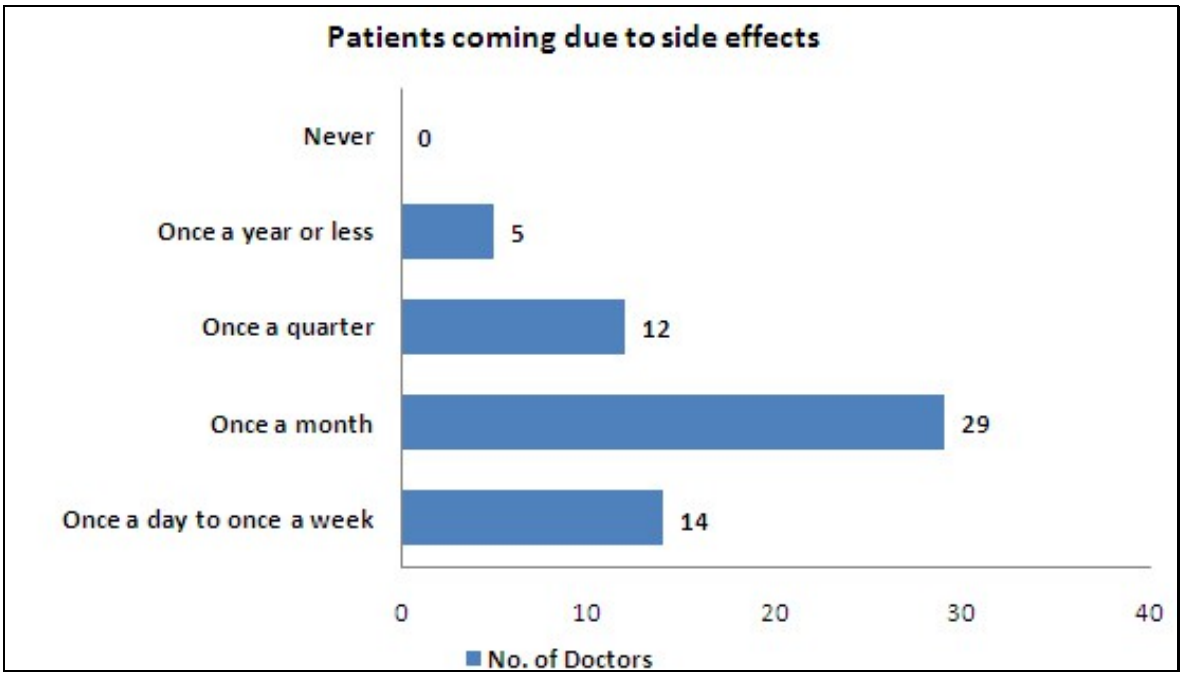
- Headache, Cold/Cough and acidity are the most common ailments for which physicians prefer giving an OTC drug



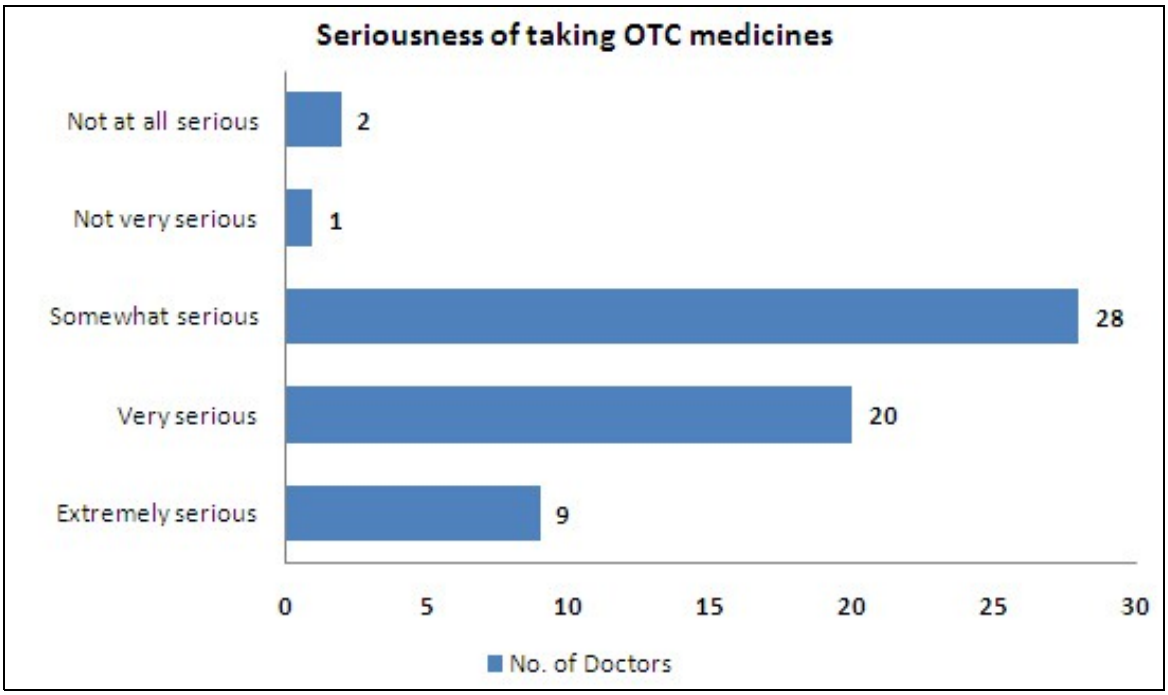
- More than 80% of the patients are not prescribed OTC drugs beacuse of their prior medical history



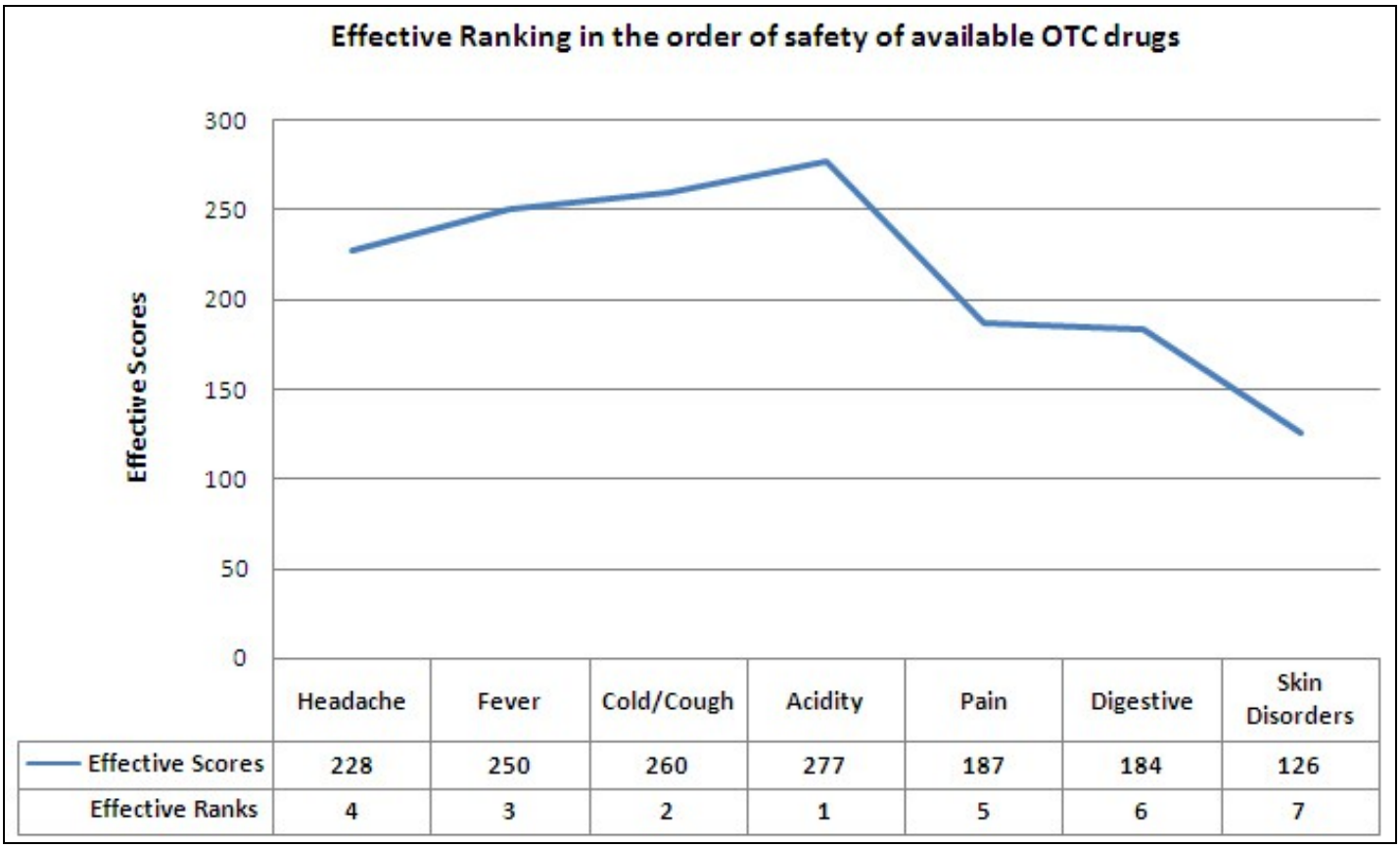
- Only 13% of the doctors feel that the information on the labels of OTC drugs is sufficient
- 98% of the doctors feel that drug-drug interactions might be a potential danger for OTC drugs
- 48% of the patients come once a month to doctor due to side effects caused by OTC drugs



- 95% of the doctors feel that the problem of taking OTCs in India is serious



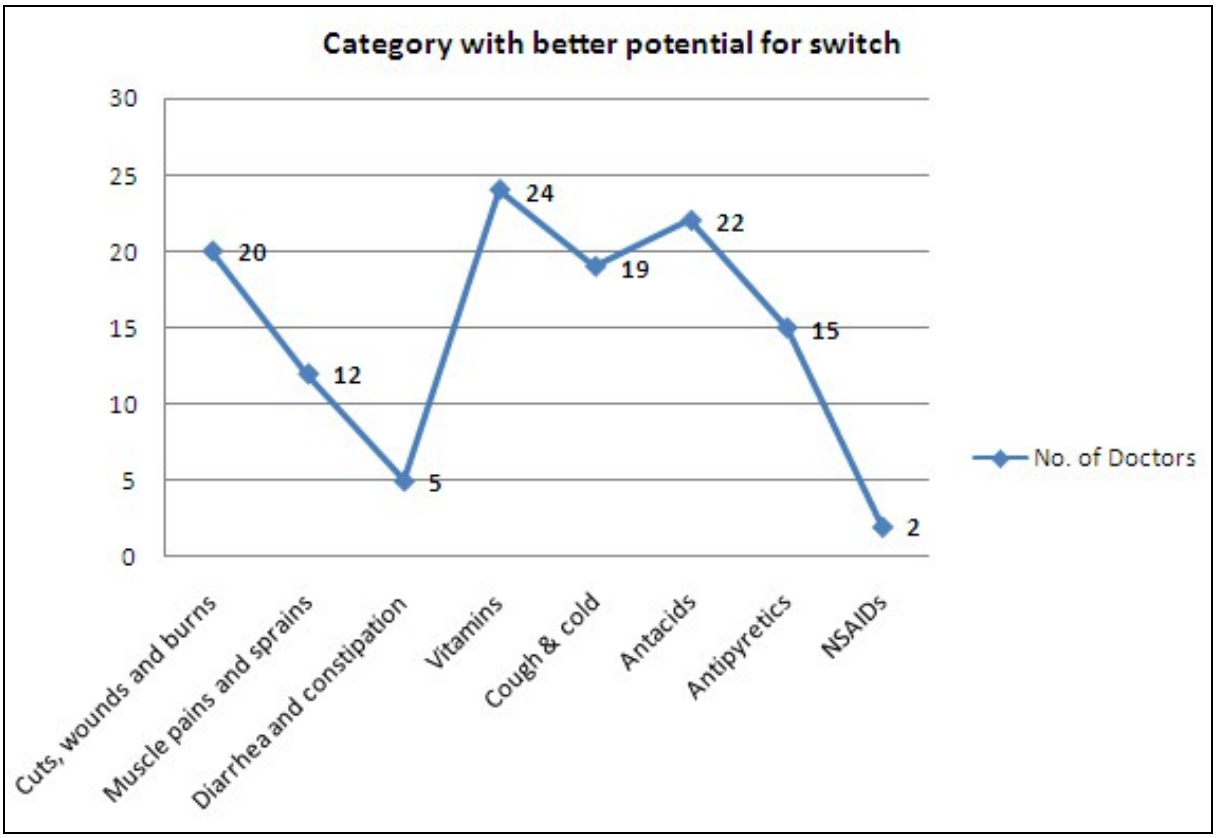
The effective ranking of the ailments in the order of safety of available OTC drugs is as follows:



	Headache	Fever	Cold/Cough	Acidity	Pain	Digestive	Skin Disorders
Effective Scores	228	250	260	277	187	184	126
Effective Ranks	4	3	2	1	5	6	7

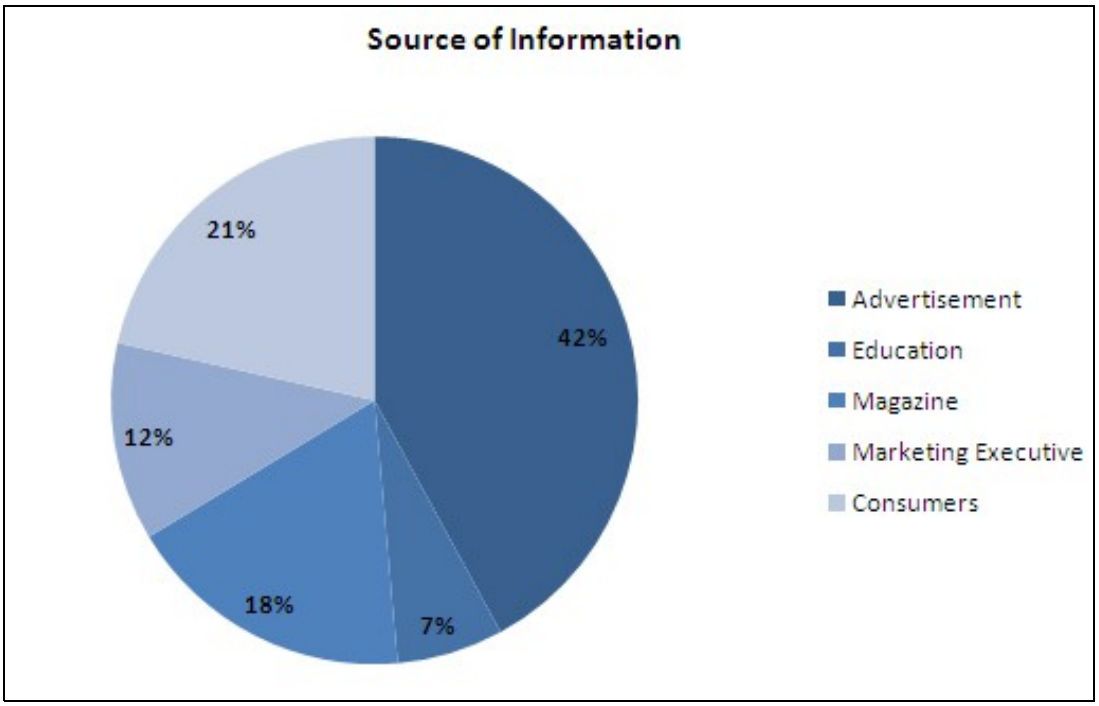
To see the calculation of the effective scores and effective ranking, click on this link

- 72% of the doctors see an opportunity for Rx-to-OTC switch in Indian pharma market
- Drugs relating to Vitamins, Antacids, Cuts, wounds and burns & Cold/Cough have a better potential to do well as an OTC drug

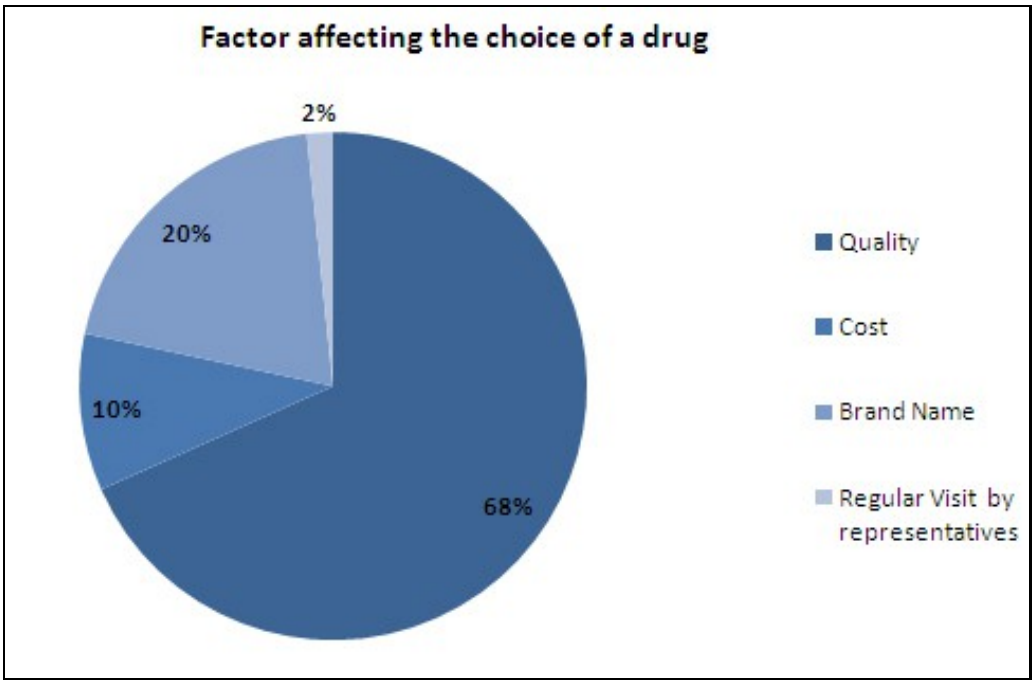


Effectiveness of marketing campaigns

- Advertisements are a major source of information for Indians on OTC drugs

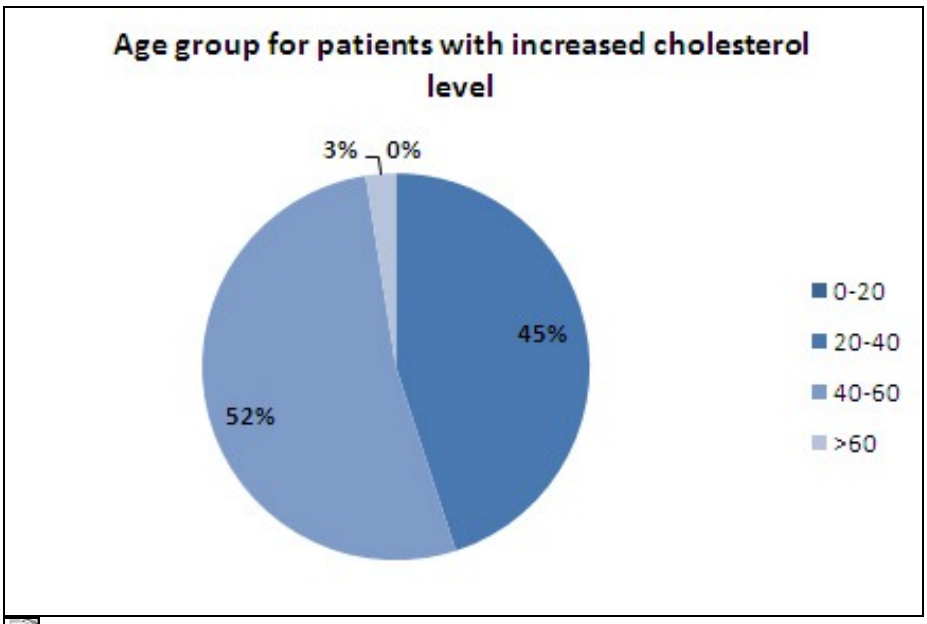


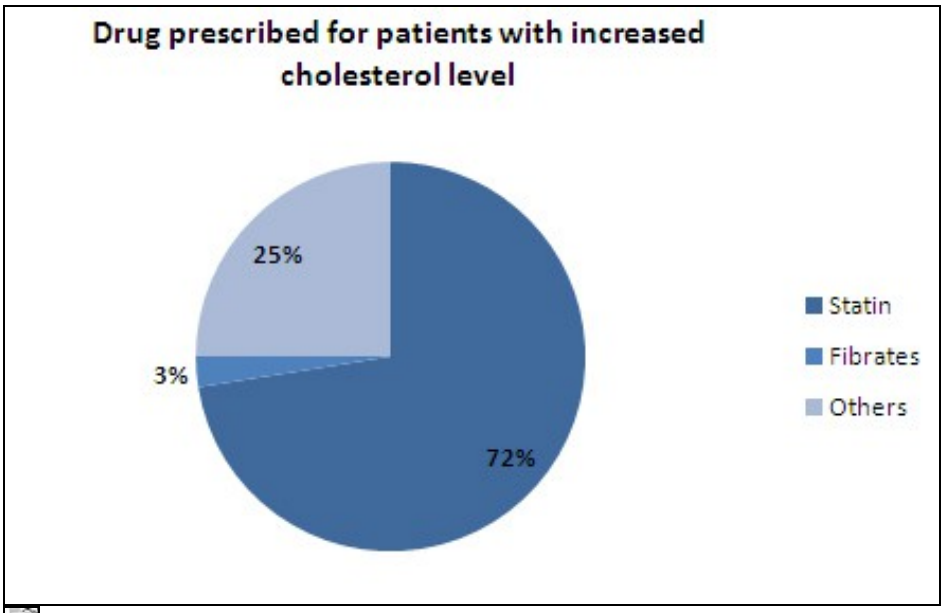
- Only 23% of the doctors permit marketing executives to market OTC products through them
- Quality is the most important factor affecting the choice of a drug



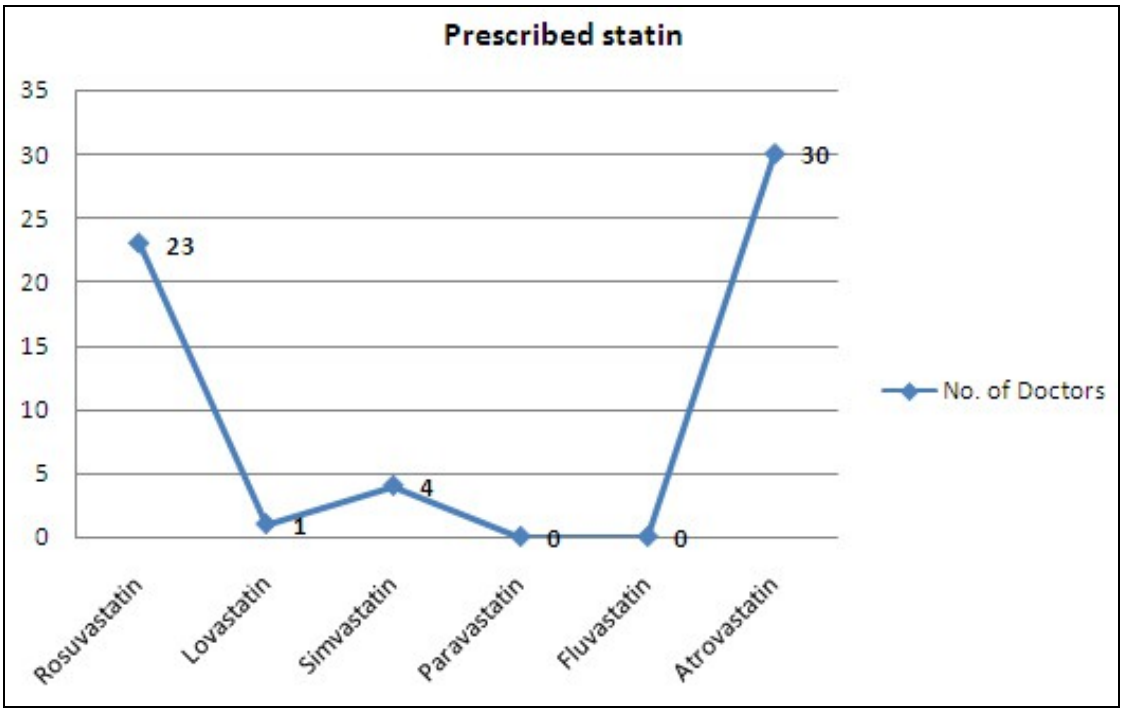
Results on Statins

- More than 50% of the patients with high cholesteral level fall in the age group of 40-60 years
- 73% of the patients with high cholesteral level are prescribed Statin by doctors

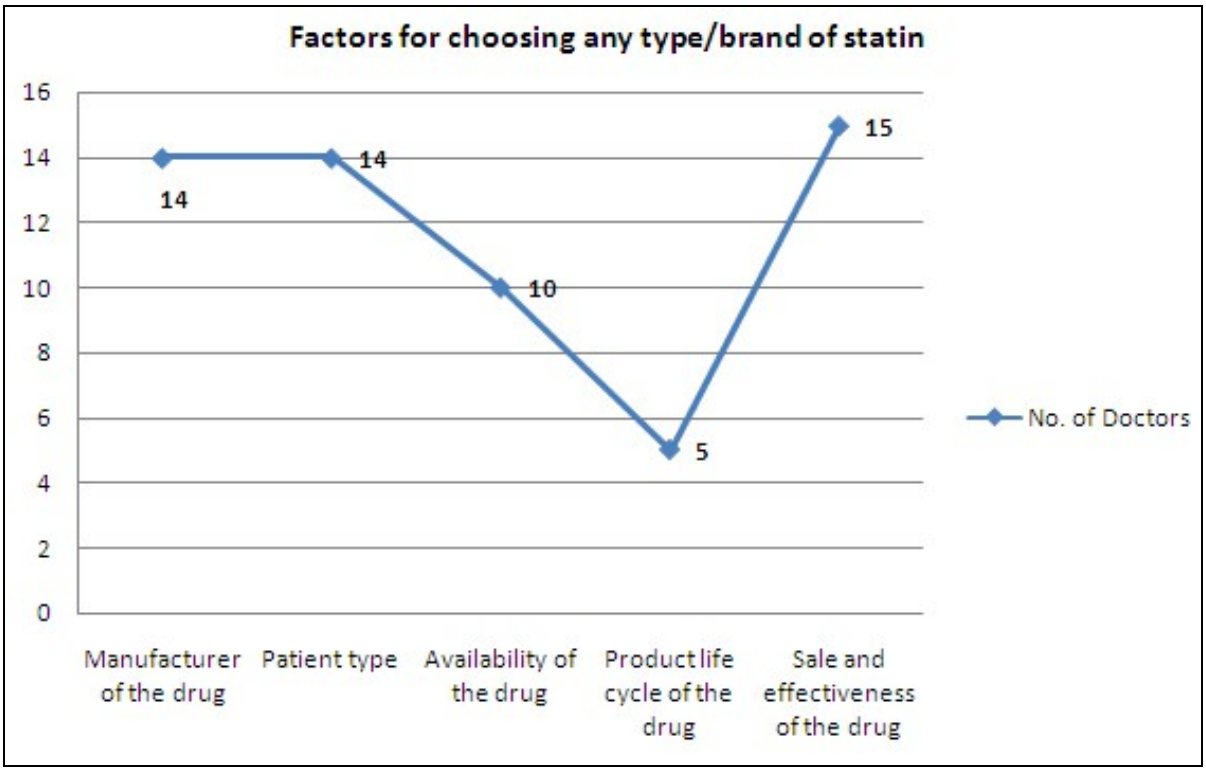




- Atrovastatin and Rosuvastatin are prescribed more than 90% of the times (whenever statins are prescribed) by doctors to patients with high cholesterol level



- Sale and effectiveness of the drug, Manufacturer of the drug and Patient type are the major factors for choosing any type/brand of statin



• Only 25% of the doctors feel that statins safe to be made available as OTC drugs for low- to-moderate risk group