Go to Market Study for "Receptol" a novel broad spectrum Anti-viral & Immune-Modulator Drug

By

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In coordination with IPSOS GSK India

Project Objectives

- To study the market of Anti viral & immune-modulators.
- To study the Doctors & consumer perception & awareness of such products and their acceptance criterions.
- To explore, compare various Routes of Distribution of Receptol
  - **The Pharmaceutical Route**
  - **Over The Counter (OTC)**
- To prepare Marketing Plan for each of the Routes

Methodology

- Visits to various Doctors and Pharmacists in metro towns.
- Consumer Survey
  - Discussion with consumer (Patients)
  - IPSOS GSK Market Research was already undertaken for the 2 Concept Testing based on 800 consumer questionnaire responses.
- Visit to NACO and its State AIDS control societies for HIV
- Visits to the Networks of PLHA
- Secondary Data from various websites.

Concept Testing

- Sample Size: 121

- Sampling Procedure: Quota Sampling
  - Singles
  - Married with Kids
  - Married without Kids
  - Married with Independent Kids

- Sampling Unit: Working consumers belonging to Socio Economic Class A

The product- Receptol

- An Immune modulator and broad spectrum antiviral used as an immune Booster
- Natural Constituents: Radha108 Nano informational Peptides & Proline Rich Polypeptides from bovine colostrum.
- Oral Spray - 9 times more effective than Pills
- Safe : No side effects with nil contraindications.
- Registered both as a Drug and OTC version

Receptol: The New Immunity Drug

Receptol® Consists of - Radha 108 Active Pharmaceutical Ingredients (API)

- API consist of Patented Nano – Informational Peptides extracted from mammalian colostrum via Ultra Nano filtration Technology having sequence id 1-8 (provided on next slide) & Proline Rich Poly Peptides (PRPs)
- PRPs & Radha-108 are a class of nano informational peptide consisting of oligo-ribonucleotide attached to a peptide molecule that act as immunity drug via immune-modulation and anti-viral/bacterial activity.
- Dosage - 3ml QDS via oral buccal spray (1 ml contains 0.03 grams of Patented Nano Peptides that can be synthetically manufactured also) and tablets, capsules & MMS drug delivery systems

The 'Biggest' thing in Industry, just may be the 'Smallest' thing – Radha 108 Nanopeptides

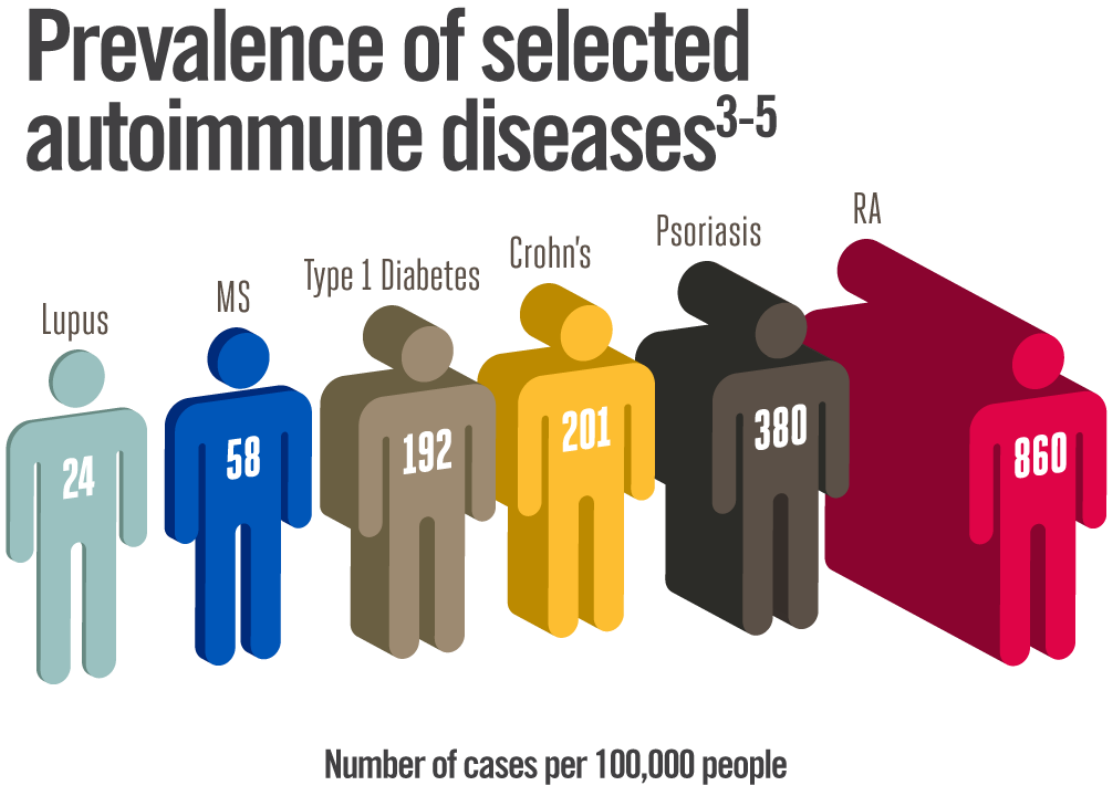
Distribution Through Pharmaceutical Route

Pharmaceutical Industry

- The Indian pharmaceutical industry is highly regulated, essentially on three aspects:
  - Patents
  - Price
  - Product quality

- The various legislations that govern the Indian Pharmaceutical Industry are:
  - The Indian Patents Act 1970 (and the amendments thereafter)
  - Drug Price Control Order (soon to be replaced by Pharmaceutical Policy 2002)
  - The Drugs and Cosmetics Act 1940

Auto immune disorders Global Market



In US alone, more than 23M people are affected by autoimmune diseases!

More than $100Billion is spent by sufferers on drugs every year!

Respiratory Disorder: Asthma Global Market

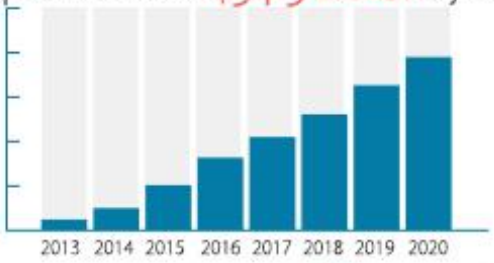
25MM alone in US

Asthma may affect as many as 334 million people.*

EXPECTED TO GROW BY MORE THAN 100MM BY 2025!

Global COPD and Asthma Devices Market

Global COPD and Asthma DevicesMarket is Expected to reach $34.3 Billion by 2020



Growing at a CAGR of 4.5 % (2014-2020)

Global COPD and Asthma Devices Market By Product Type

- Inhalers
  - Drug powder inhalers (DPIs)
  - Metered Dose Inhalers (MDIs)
  - Soft Mist Inhalers (SMIs)
- Nebulizers
  - Compressor nebulizer
  - Ultrasonic nebulizer
  - Mesh nebulizer

Global COPD and Asthma Devices Market By Geography

Asia-Pacific, North America,LAMEA

Europe

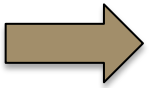
Fastest Growing Segment at a CAGR 4.8% (2014-2020)

*Source: www.GlobalaAthmaReport.gov

Allergies Global Market

Adults

Children



30% adults and 40% of children worldwide are affected by allergies!

$25Billion is spent on Asthma drugs annually which has gone up by 50% since 2009!

*Source: www.GlobalaAthmaReport.gov

AIDS Global Market :

HIV is a major threat affecting ~40m people worldwide and the sales for HIV drugs are expected to increase steadily

1.2M only in US

36.9 MILLION

people worldwide are currently living with HIV/AIDS.

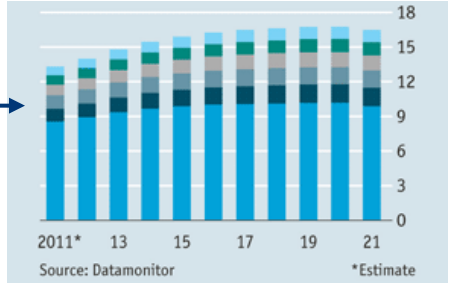
The vast majority of people living with HIV are in low- to middle-income countries, particularly in Sub-Saharan Africa.

2.6 MILLION CHILDREN

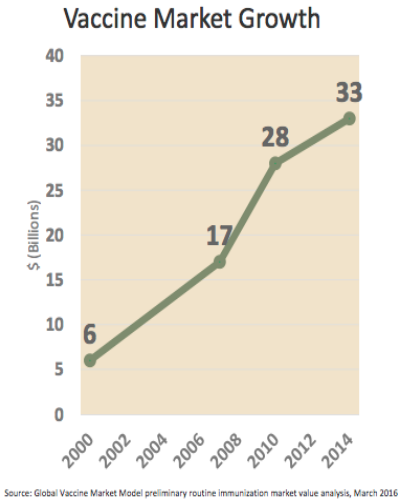
worldwide are living with HIV. Most of these children were infected by their HIV-positive mothers during pregnancy, childbirth or breastfeeding.

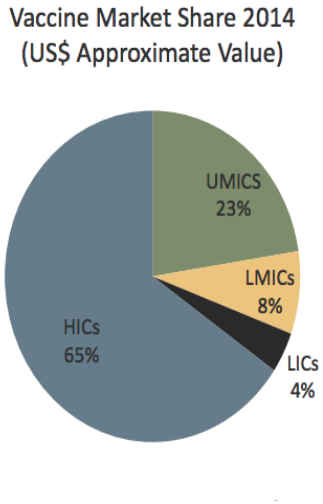
Source: www.aids.gov

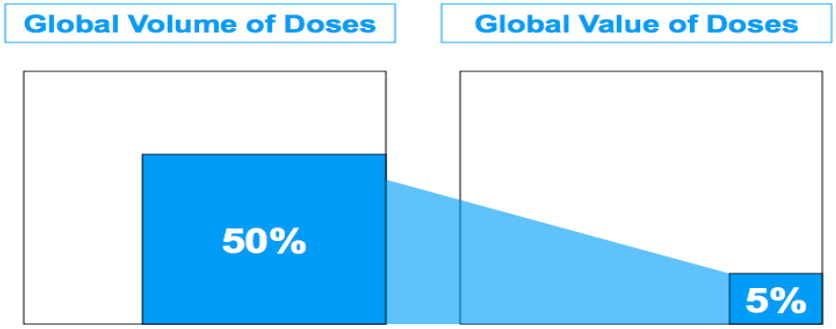
Forecast of HIV drug sales ($Billion)



Vaccine Global Market and its distribution



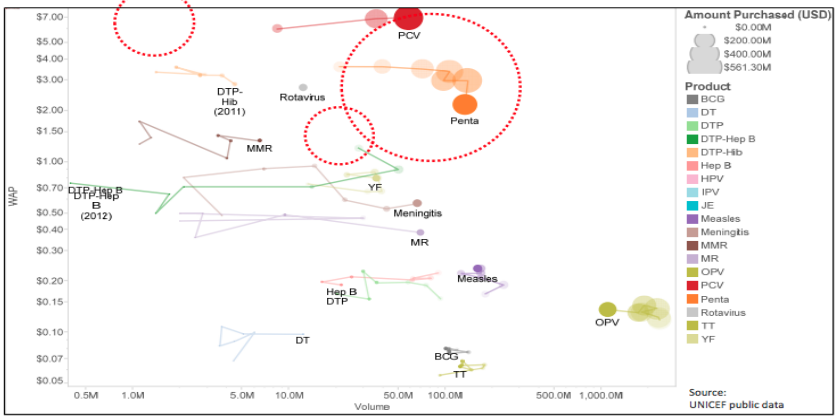




50% of the vaccines bought (volume wise) signify only 5% of value overall.

- **Positive trends**
  - **- Immunizations: on the top of the agenda: DOV ands GVAP**
  - **- Promising vaccine pipeline, R&D**
  - **- Growing support: GAVI partners + Gov funding**
  - **- Multiple initiatives, PDPs and PPPs**
  - **- New players on supply and funding**
  - **- More WHO PQ vaccines leading to competition, price decrease**
  - **- Strategic role of UNICEF SD and PAHO and increasing role of funders**

- **Concerns :**
  - **Oligopoly, limited supply for DC and Shortage risks**
  - **Upstream factors : Technology transfer and IPRs, R&D for most needed vaccines, DCVM R&D capacity , ..**
  - **New vaccine costs and prices**
  - **Financial sustainability ? Govt responsibilities role**
  - **Future of International initiatives**
  - **Future of Emerging Manufacturers**
  - **Impact of the financial crisis?**



Consumer Analysis

- In Pharma sector drugs are not directly marketed to the patients.
- Doctor's prescription is mandatory
- The Target population: Doctors (depending on their prescription trends)

Competitor's Brand Analysis

- Antioxidants given to increase immunity (Many Pharma MNCs)
- Immuneace (Meyer)
- Immunemode (Merck)
- Nectra (Lupin)

No direct competitor for Patented Receptol

Positioning

As Broad Spectrum Anti viral

&

Immune-modulator

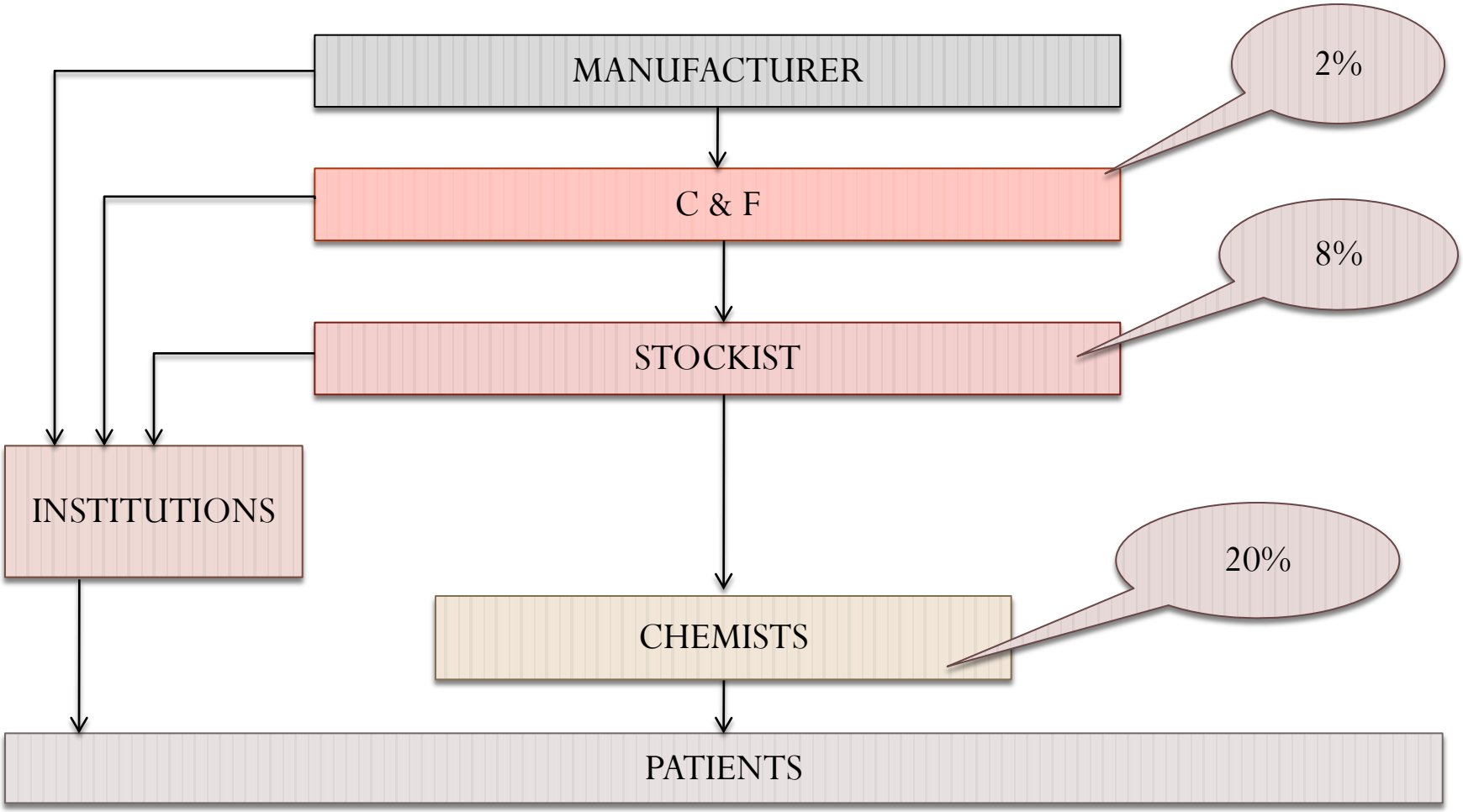
for

treatment of many chronic diseases.

Act as mono-therapy for commonly occurring viral infections.

PHARMACEUTICAL DATA ON RECEPTOL

DOSAGE AND ADMINISTRATION	4 Sprays of 0.75ml metered dose (3ml), two each on each side of inner cheek 4 times daily
ROUTE OF ABSORPTION & DISTRIBUTION	• API (PRPs) absorbed through the buccal mucosa • Crosses blood brain barrier due to low mol. wt below 2kDa. • Distributed all over the body through the blood streams.
INDICATIONS	• Treatment of HIV & for associated recurrent infections. • Immunity enhancer for immune disorders like Communicable disease (Swine Flue, Influenza, TB, Dengue, Hepatitis), Cancer, Asthma, Rheumatoid Arthritis
CONTRAINDICATIONS	• Proven to be safe in acute as well as chronic use. • No incompatibility along with any other medication. • No minor or serious contraindication reported.
WARNINGS & PRECAUTIONS	None, Since its over dose does not harm anyone even neonates
ADVERSE EFFECTS	No adverse effects observed.
STORAGE	Keep in cool & dry place. Keep under refrigeration once the bottle is opened and consume within 30 days after opening.


MANUFACTURER
2%
C & F
8%
STOCKIST
INSTITUTIONS
20%
CHEMISTS
PATIENTS

Promotion

- Conferences/Continuous Medical Education (CME)
  - Hold lectures to make the doctors aware of the product, Patents, its feature, mode of action, and global clinical study results
- Free samples & promotional gift vouchers to doctors
- Information brochures to doctors via electronic & hard copies
- Incusion in the National Health Program like WHO funded National AIDS Control organizations

Pricing

- Suggestive Price by Doctors: Rs. 1500/month (3 bottles per month)
- Generic Substitute's price: Rs.1000-1500/month

Anti-Viral Distribution

Why Separate Approach For Anti-Viral?

- Stigma attached to the Disease.
- Distribution channel which would primarily by States.
- Specialized Doctors in Private Practice for treatment of patients.

AIDS/Antiviral : Statistics and Issues

- 2.5 million HIV+/AIDS cases in India
  - 0.5 million on ART in 192 ART centers (govt.) and private clinics
  - 2 million not on ART and can be given Receptol for opportunistic infections
- NACO guidelines followed in treatment of AIDS/HIV+ patients
- Treating opportunistic disease like HIV related prolonged Diarrhea, Cough, Cold, Fever, TB, Cancer (Kaposi Sarcoma), Oral thrush, Skin & Vaginal Rashes.

Pricing of HIV ART Drugs

- Presently ART drugs cost Rs. 1000-9000/ month
- Patients treated for opportunistic infections which may cost many thousand Rupees
- Projected Minimum Price of Receptol 125 ml bottle : Rs. 500/-

Target Segment

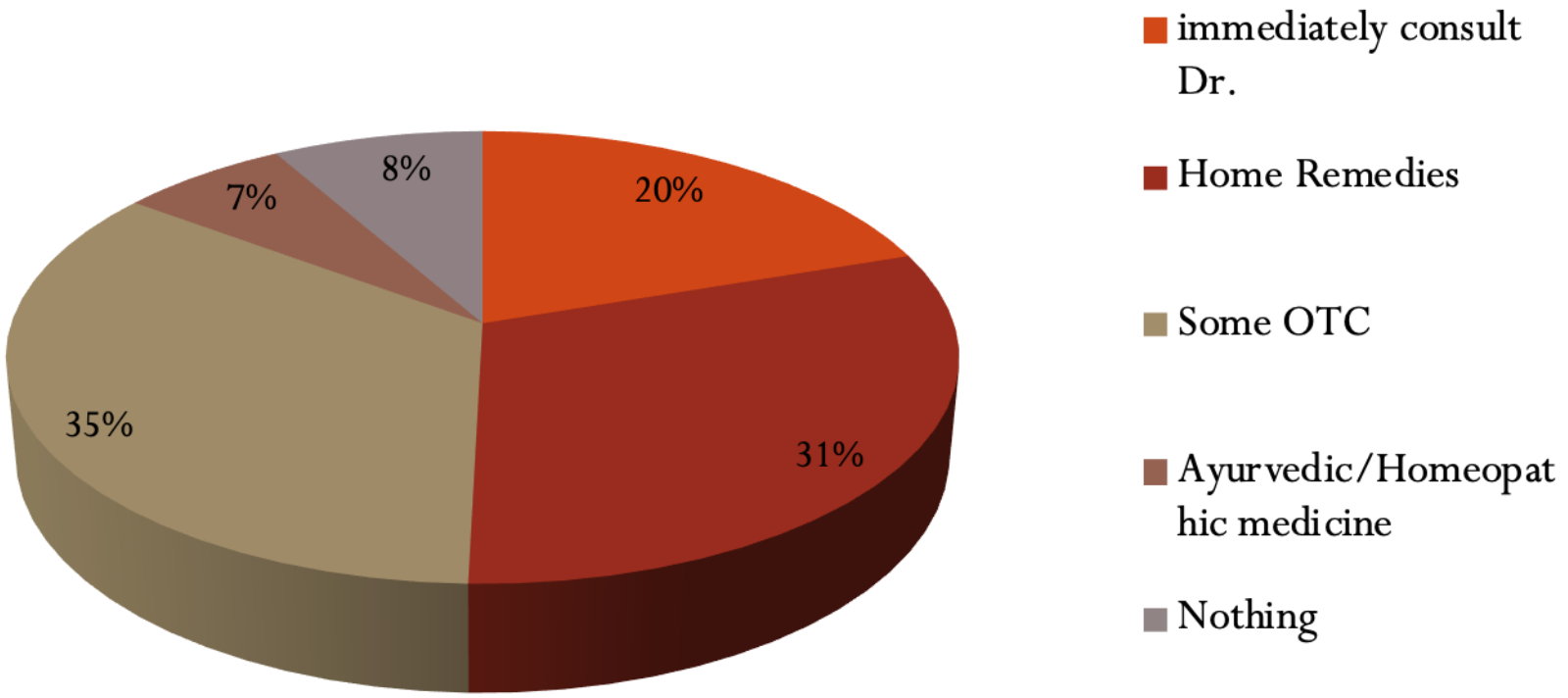
- Socio Economic Class A
- Cities: Ahmedabad, Mumbai, New Delhi
  - High percentage of SEC A population *
- Target segment size: 5.2 million households *
- Rationale of choosing the target segment:
  - Diffusion of innovation#
  - Share of wallet *
  - Busy lifestyle

*Source: Marketing white book, 2006

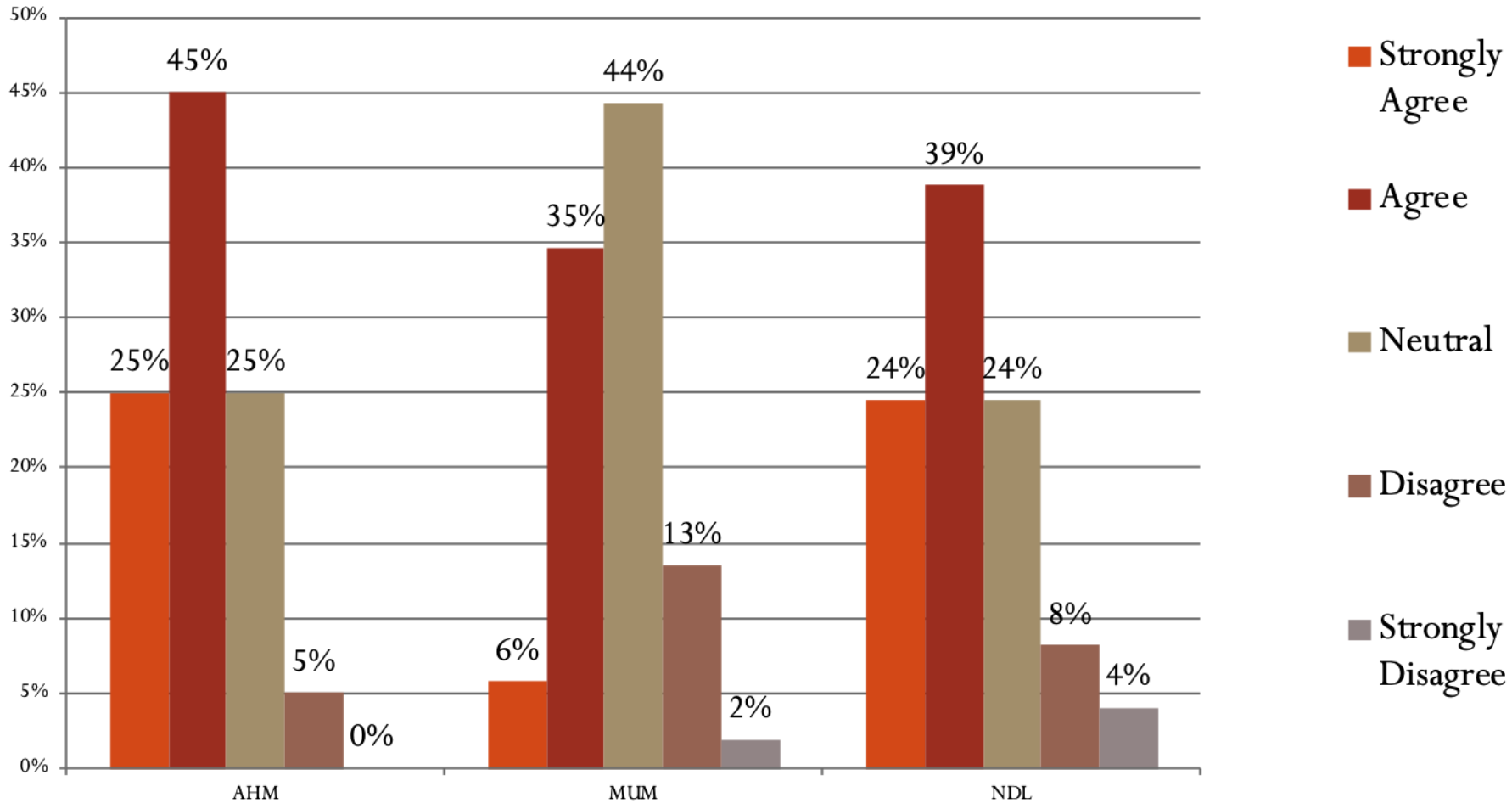
Reference: Rogers, Everett

Consumer Analysis for OTC Route

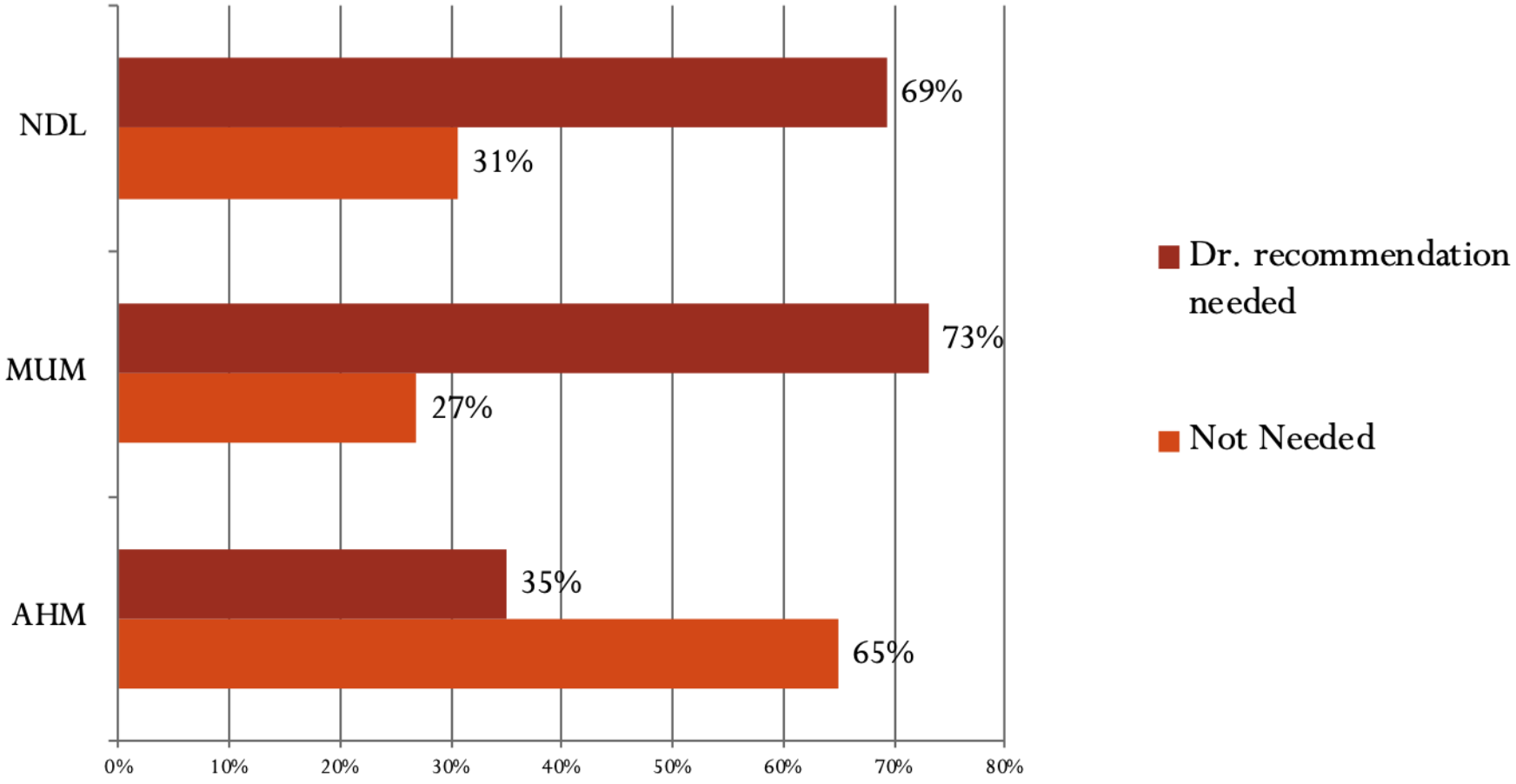
- Mostly Bank upon Home remedies and pre-established OTC formulation when fall sick



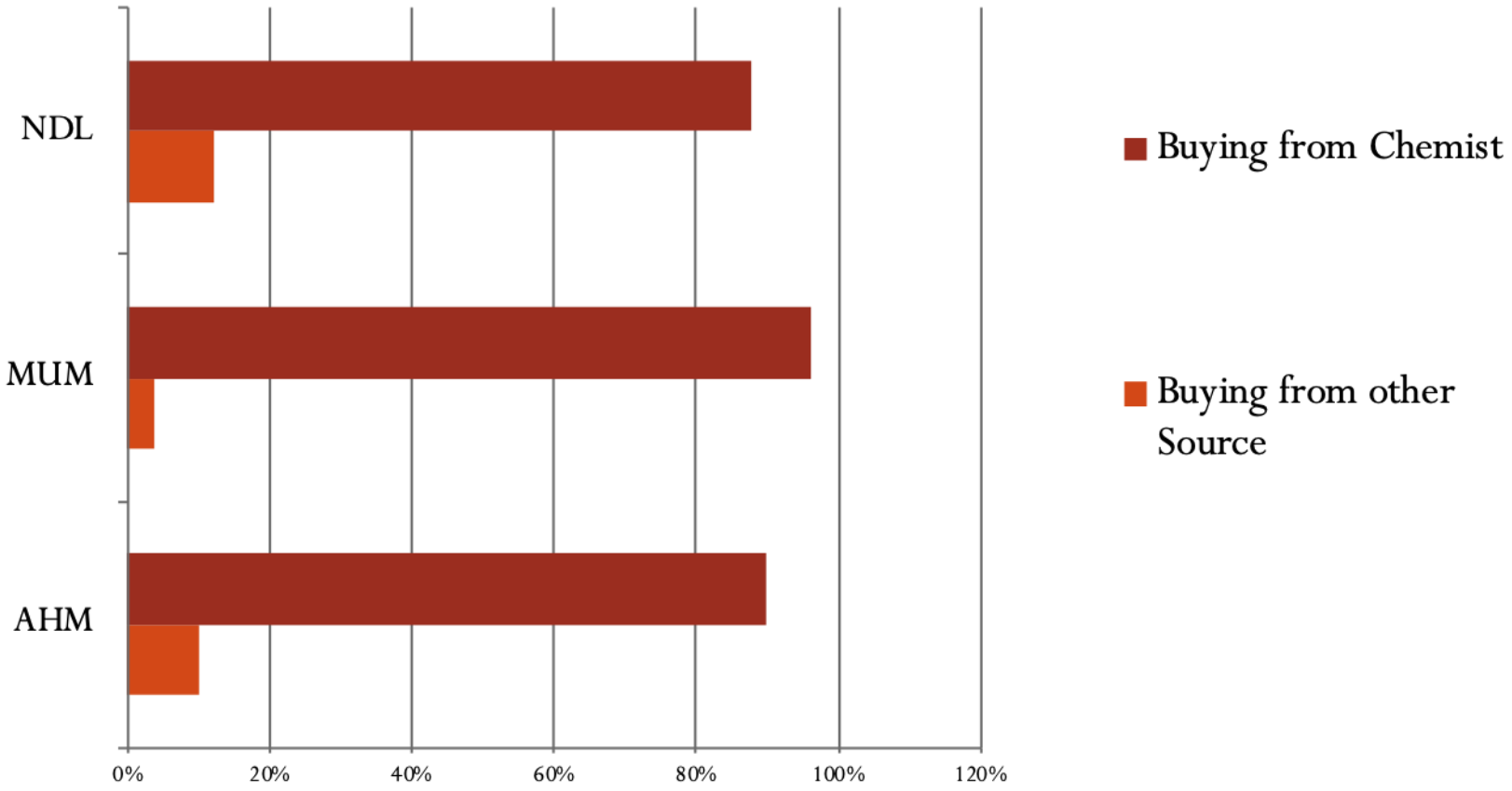
- Believe that health drinks enhance their immunity



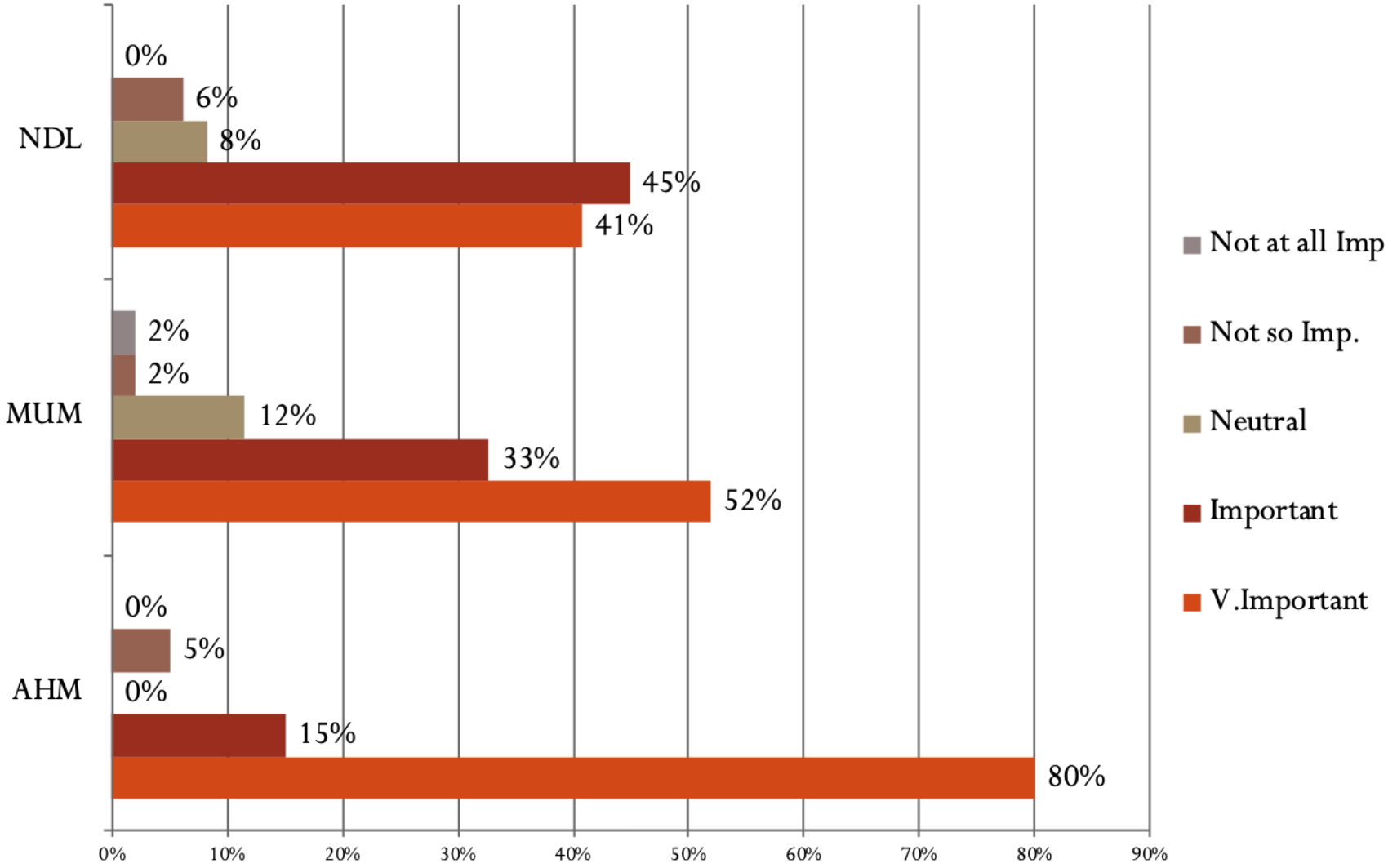
- Doctors' recommendation is very important to buy a new health product



- Preferred site of buying a health product is a chemist shop

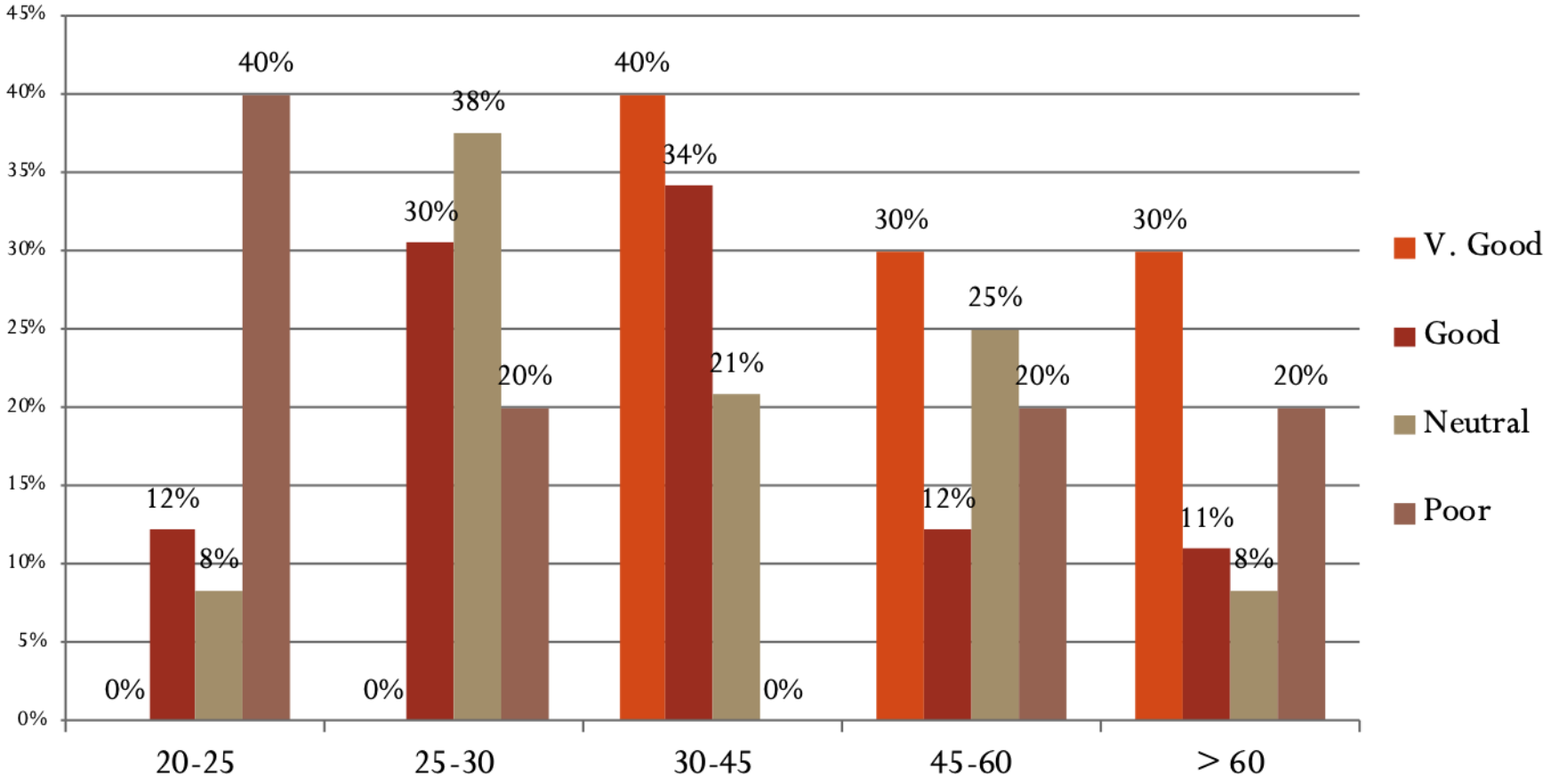


- Importance of brand for health products

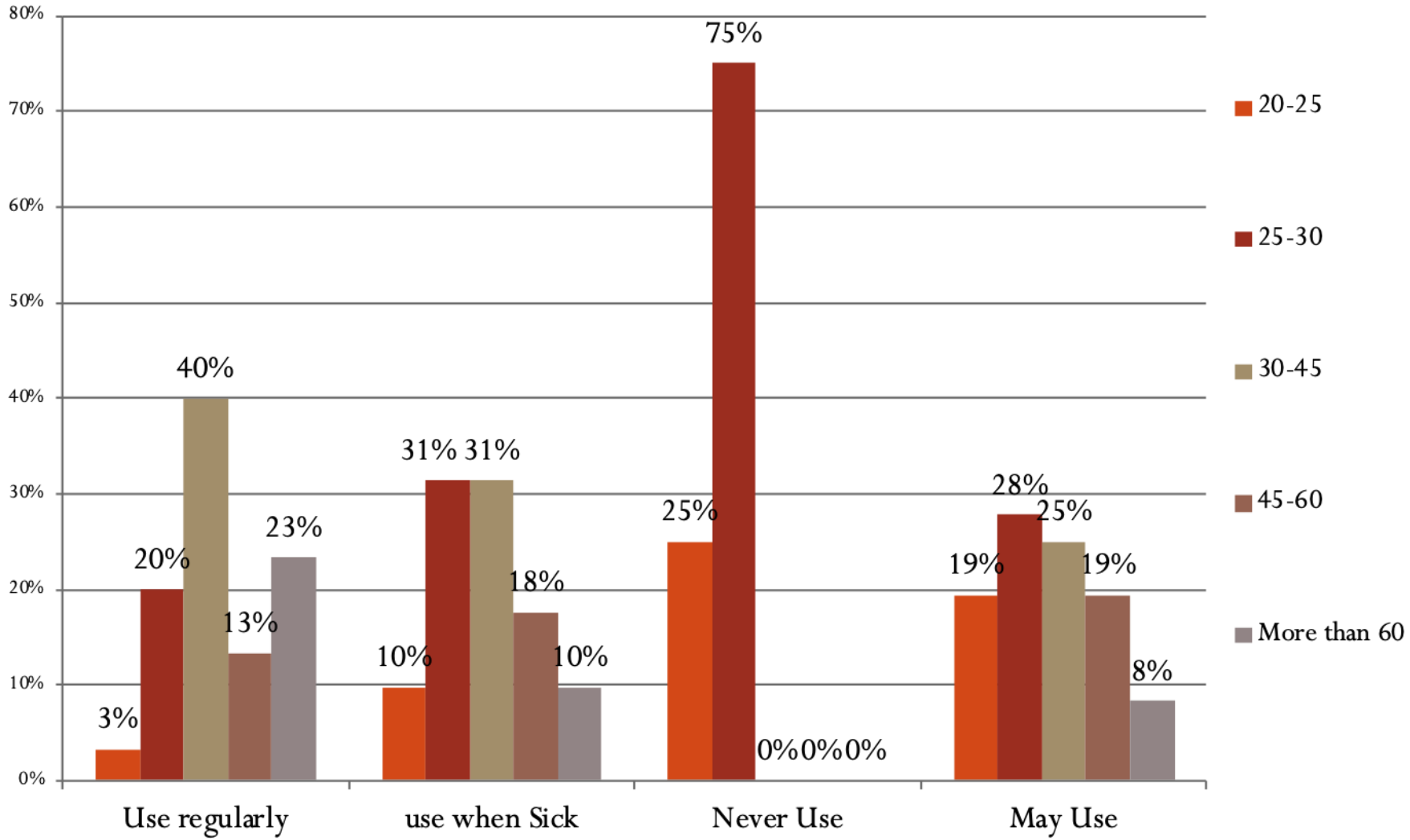


Target Population

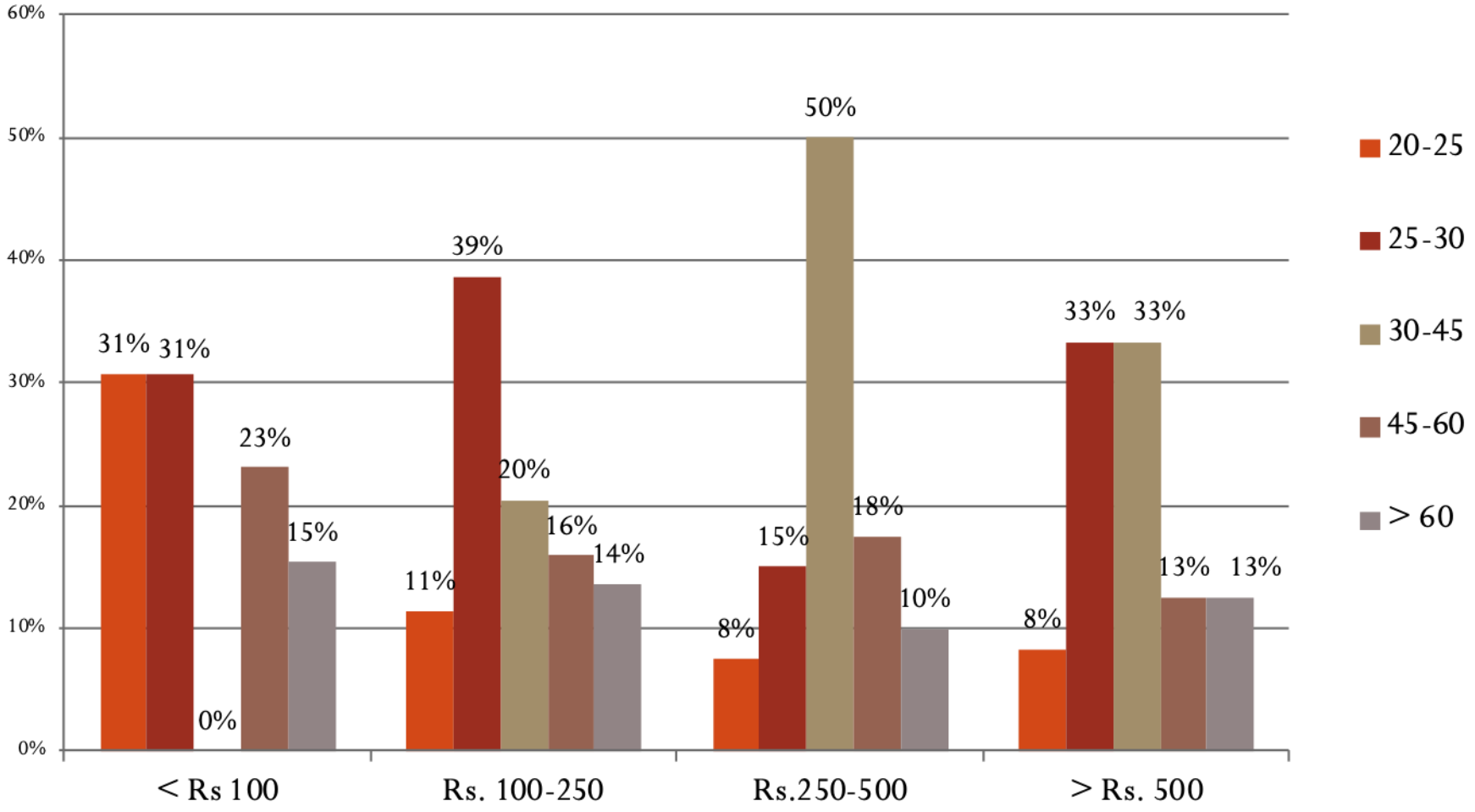
- Age group of 30-45 is most receptive to OTC Brand



- This group is most willing to use OTC Brand regularly



- This group also spends most on health and OTC products

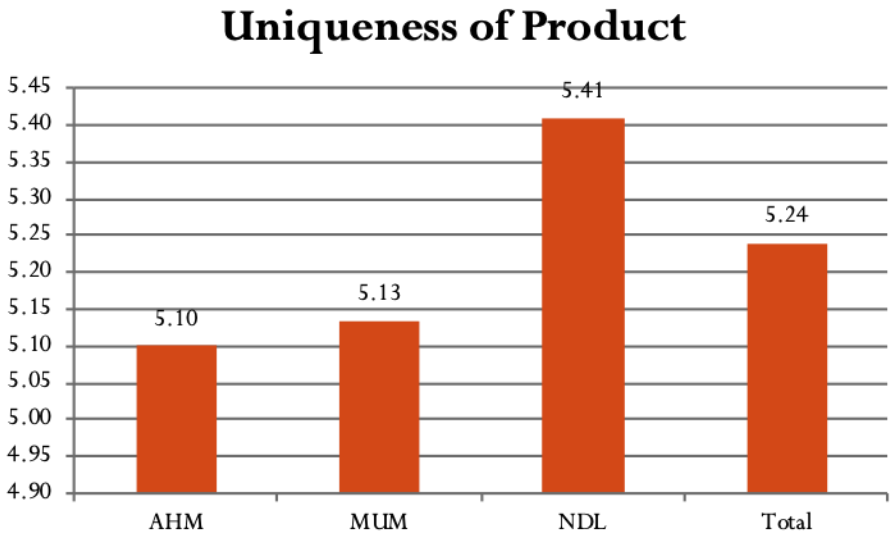


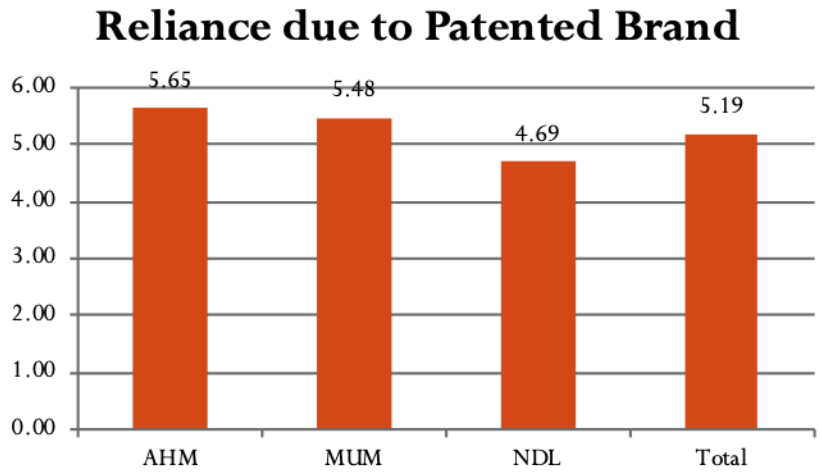
Target Group

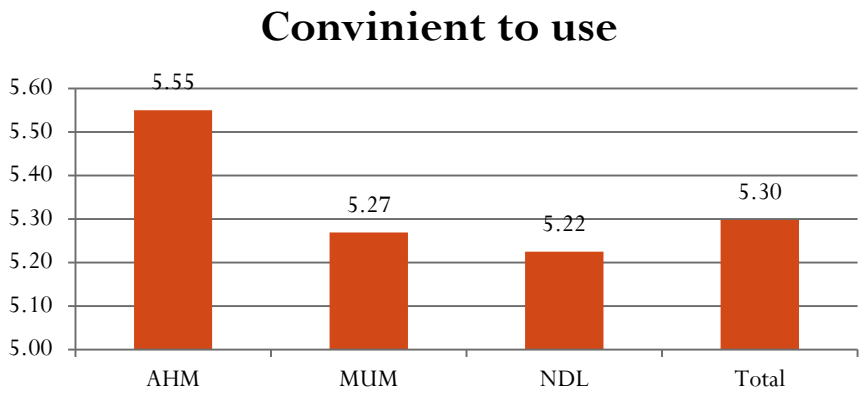
- Provide protection against common infection and very helpful to
  - Children
  - Elderly
  - Working members of the family

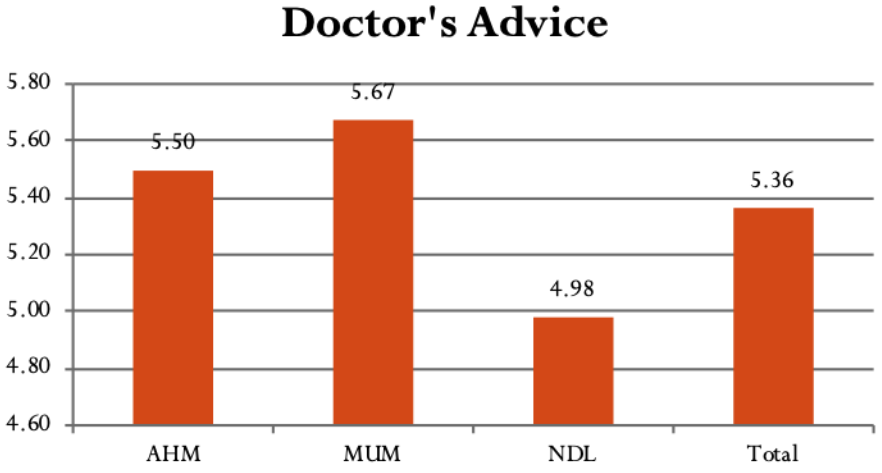
- Apt for the people who
  - Have weak immune system (suffer by recurrent cold and cough)
  - Don't have time or easy mode to take proper care of their health

Consumer opinion about OTC Brand

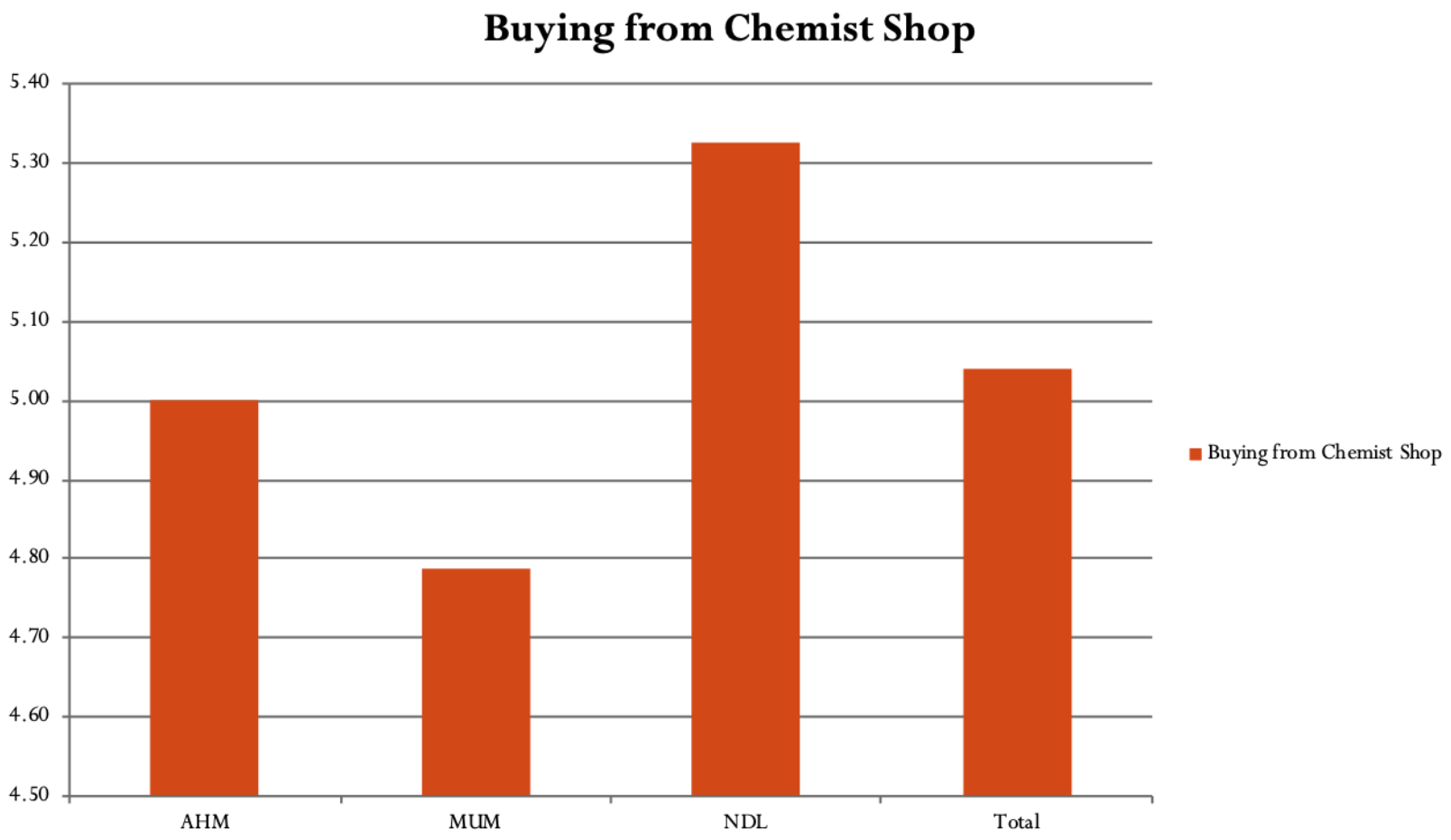




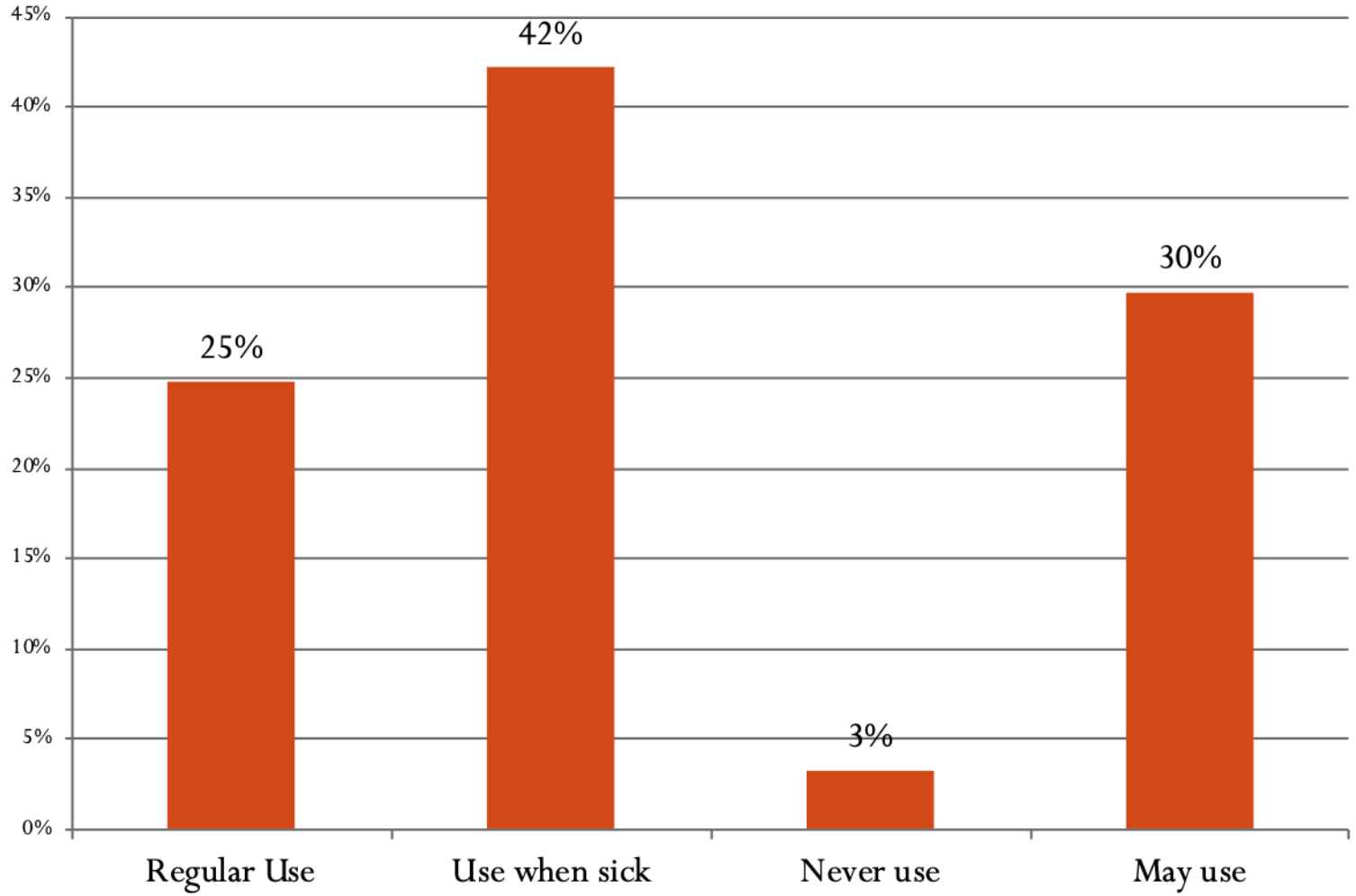




Preferred spot for buying OTC Brand



Expected usage pattern of OTC Brand by consumers



Positioning as OTC

- Product for general wellbeing that helps in building body's Immune System naturally to prevent infections.
- Suitable for the whole family, No Age Bar.
- Safe, Tested and reliable product (using Patented brand)

Promotion

- Concept selling via creating awareness about Patented Nano informational Peptides & PRP extracted from bovine colostrum
  - Conferences/CME Seminars with doctors to make them aware about the Brand
  - Formation of Medical Promotion Teams for Rapport building with Doctors
  - Billboards, light-boards, signboards at major sites
  - Hot air balloon campaign at major sites.
  - Press releases showing efficacy and safety
  - Social Media Marketing

Contd.

- At the time of launch of OTC Brand:

  - Advertisement in leading Local language & English News Papers, magazines such as Times of India, India today, Reader's Digest etc.
  - Advertisements at fitness centers and gyms
  - Endorsements from leading & famous doctors and hospitals

Challenges of current HIV therapy

ART & DOT Drug regimen are complicated by

- Cost of treatment
- Adherence potential
- Pill & bill burden: no single drug mono-therapy trials done globally
- Drug-drug interaction
- Co-morbidities
- Treatment failure due to resistance to drugs, MDR/XDR TB
- Serious side effects

Several studies have documented that one year after initiating ART 40-50% patients have actually changed their first line regimen for various reasons. Studies include:

➢ Macroft A et al. AIDS 2001;15:185-94. Clinical toxicity has been proved to be a major cause for discontinuation/changing ART

➢ Foma, F. et al Journal of acquired immunodeficiency syndromes 2007,vol. 44, pp. 456-462

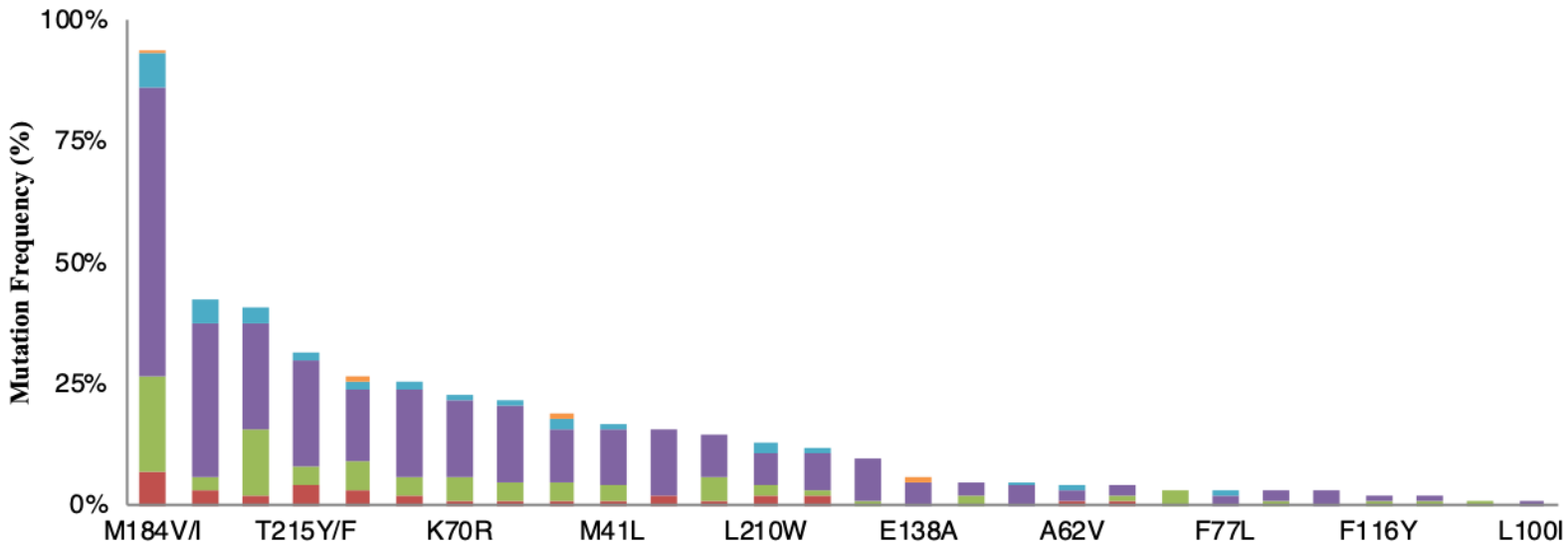
➢ Robbins, GK et al. Journal of acquired immune deficiency syndromes 2007,vol. 44,no1, pp. 30-37

Drug resistance after first line failure: India & Africa

Stanford Resistance Score	ZDV	D4T	TDF	DDI	3TC	EFV	NVP	ETR	LPV/r
Hyper-susceptible	44 (40%)	35 (32%)	41 (37%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Susceptible	14 (13%)	9 (8%)	23 (21%)	40 (36%)	5 (5%)	1 (1%)	1 (1%)	1 (1%)	109 (98%)
Potential Low-level	3 (3%)	5 (5%)	12 (11%)	7 (6%)	1 (1%)	0 (0%)	0 (0%)	19 (17%)	1 (1%)
Low-level Resistance	9 (8%)	22 (20%)	11 (10%)	20 (18%)	0 (0%)	0 (0%)	0 (0%)	25 (23%)	1 (1%)
Intermediate Resistance	21 (19%)	23 (21%)	22 (20%)	27 (24%)	5 (5%)	28 (25%)	0 (0%)	57 (51%)	0 (0%)
High-level Resistance	20 (18%)	17 (15%)	2 (2%)	17 (15%)	100 (90%)	82 (74%)	110 (99%)	9 (8%)	0 (0%)

Reference:
Bartlett JA, Ribaudo HJ, Wallis CL, Aga E, Katzenstein DK, Stevens WS, Norton MR, Klingman KL, Hosseinipour MC, Crump JA, Supparatpinyo K, Badal-Faesen S, Kallungal BA, Kumarasamy N. Lopinavir/ritonavir Monotherapy After Virologic Failure of First-line Antiretroviral Therapy in Resource-limited Settings. AIDS. 2012 2012 Jul 17;26(11):1345-54. PMID 22441252

ART drug resistance mutations among 120 patients from India & S. Africa



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Global Safety & Efficacy Studies on HIV Positive Subjects

Safety and Efficacy Achieved by Global Trials:

- Phase I : 12 cohort 30 days in Ohio, USA—Completely Safe
- Phase II : 30 cohort 90 days in Nairobi, Kenya—Highly effective with no side effects
- Phase III : 60 cohort for 365 days in Rwanda, Africa—Highly effective with no side effects

- Phase III Indian Safety & Efficacy Mono Therapy Clinical Trials with Receptol® Nano Peptide by Government of India, Ministry of Health/National AIDS Control and Monitored by Indian Council of Medical Research/NARI*, a US PATH accredited org.

- Study I: 50 HIV Positive Patients at Tertiary Care LTMG Hospital Sion, Mumbai (Clinical trial registry No. : CTRI-2012-08-002931)

- Study II: 51 HIV Positive Patients at Tertiary Care LTMG Hospital, Sion, Mumbai (Clinical Trial registry No. : CTRI-2012-09-002959)

**The study was fully controlled, conducted and sponsored , by Govt. of India with Indian Council of Medical Research proposed Protocols.*

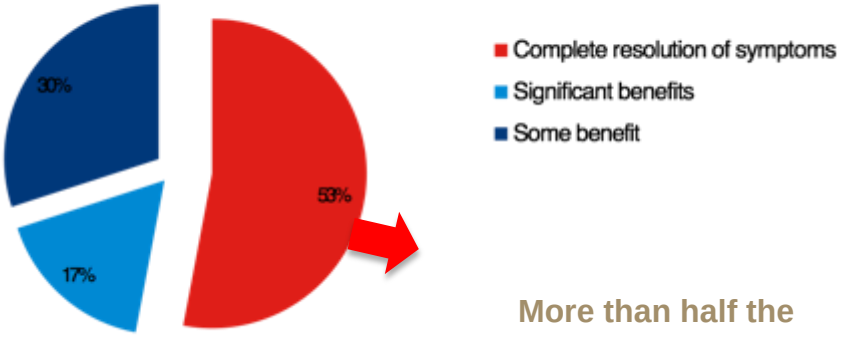
SUMMARY - GLOBAL SAFETY & EFFICACY STUDY ON AIDS SUBJECTS

KEY DIMENSIONS	PHASE I, II & III INTERNATIONAL TRIALS	INDIA PHASE III STUDY 1	INDIA PHASE III STUDY 2
Phase	Phase I - HIV trial, US Phase II - HIV trial, Nairobi, Kenya Phase III - HIV trial, Rwanda	Phase III validation trial by GOI on HIV patients, Standalone monotherapy	Phase III validation trial by GOI on HIV patients, Standalone monotherapy
No. of patients	Phase I - 12 cohorts Phase II - 30 cohorts Phase III - 60 cohorts	50 HIV seropositive patients	51 HIV seropositive patients
Duration	30 to 365 days	180 days	180 days
Compliance	Very good	Very good	Very good
Side effect	None	None	None
Weight gain	6 lbs average gain	4.73 kg per patient, $p<0.05$	4.68 ± 1,9 kg per patient, $p<0.001$
Clinical symptoms	90 days relief from symptoms	Improved within 3 weeks from starting of therapy	Improved within 3 weeks from starting of therapy
CD4 cell count	Phase II: Average by 31	Average by 51, median CD4 cell count from 312 to 363 ($p = 0.06$)	On an average by 27 ($p = 0.042$)
HIV Viral load	Phase II: Mean HIV log viral load from 4.6 to 2.5	Mean HIV log viral load from 4.63 to 4.18 ($p = 0.001$)	Mean HIV log viral load from 4.41 to 4.02 ($p = 0.009$)

US Studies on Immunity Disorders

Allergies

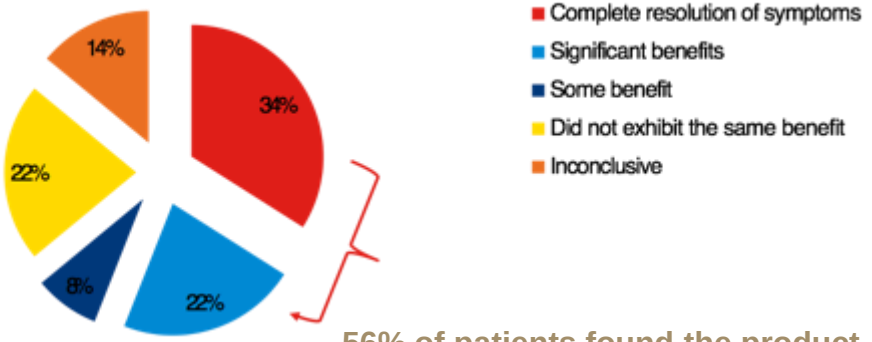
Reporting Patients:	24
Duration of Treatment:	6 months



More than half the respondents experienced complete resolution of symptoms!

Rheumetoid Arthritis

Reporting Patients:	63
Duration of Treatment:	6 months

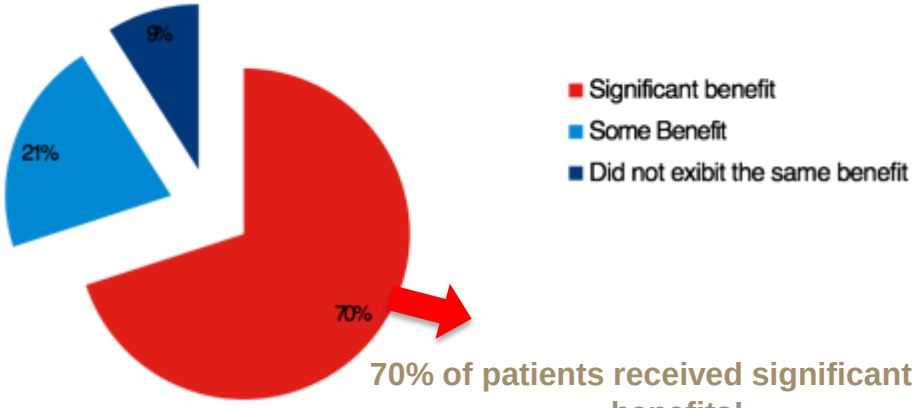


56% of patients found the product to be highly effective!

US Studies on Immunity Disorders

Chronic Fatigue Syndrome

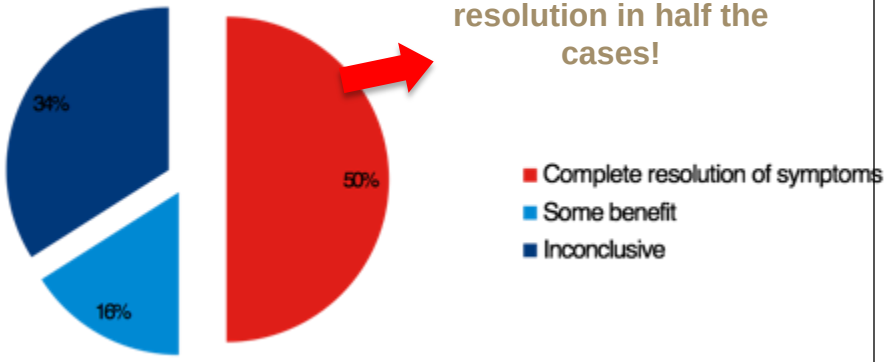
Reporting Patients:	108
Duration of Treatment:	6 months



70% of patients received significant benefits!

Endometriosis

Reporting Patients:	106
Duration of Treatment:	6 months

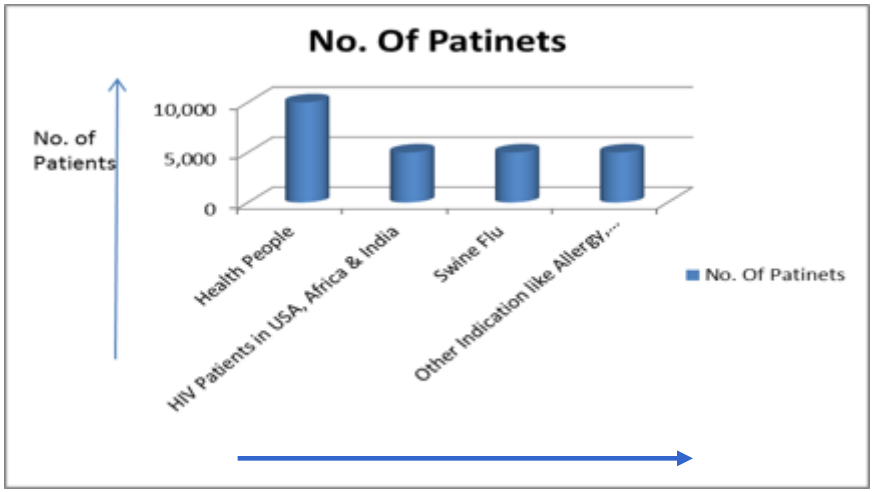


For Endometriosis, complete resolution in half the cases!

PHASE 4 : Meta Analysis on 25,000 Patients

- Meta Analysis is a combined Statistical analysis of 25,000 subjects across HIV, Swine Flu, Allergy/Asthma, Rheumatoid Arthritis, Endometriosis and other Non Communicable Diseases which shows an increase in weight gain as an indication of overall wellness, Safety and Efficacy of Receptol®

Sr.No.	Stand Alone Receptol Therapy in Global clinical studies	No. of Patients
1	Healthy people	10,000
2	HIV Patient in USA, Africa, India	5000
3	Swine Flu	5000
4	Other Indications like allergy, asthma, Rheumatoid Arthritis, Chronic Fatigue Syndrome, Endometriosis Study etc.	5000

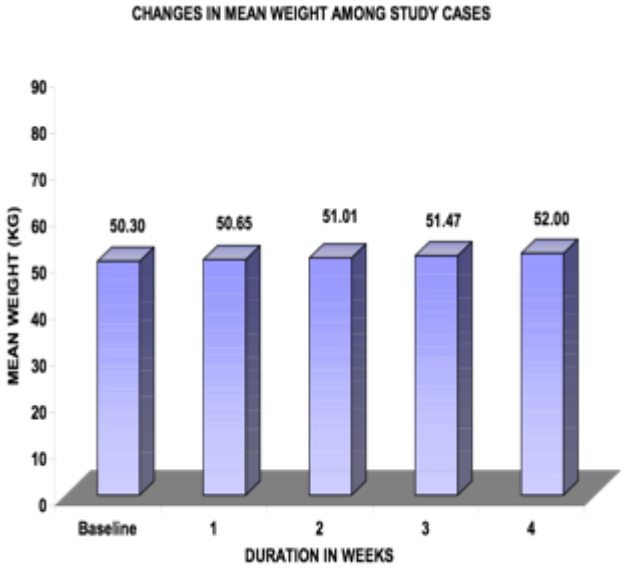


Stand Alone Receptol® Therapy in Global Clinical Studies

Efficacy & Safety on a Healthy Population of 10,000 Subjects

CHANGES IN MEAN BODY WEIGHT AMONG STUDY CASES

Duration (Weeks)	$\bar{X}$ Mean weight (± SD) (N = 10000)
Baseline	50.30 ± 10.02
1	50.65 ± 10.01
2	51.01 ± 09.96
3	51.47 ± 09.94
4	52.00 ± 09.96
Mean Diff. (Baseline – Wk1) (P value)	*00.35 ± 00.66 (0.001)
Mean Diff. (Baseline – Wk2) (P value)	*00.71 ± 01.24 (0.001)
Mean Diff. (Baseline – Wk3) (P value)	*01.17 ± 01.95 (0.001)
Mean Diff. (Baseline – Wk4) (P value)	*01.70 ± 02.15 (0.001)

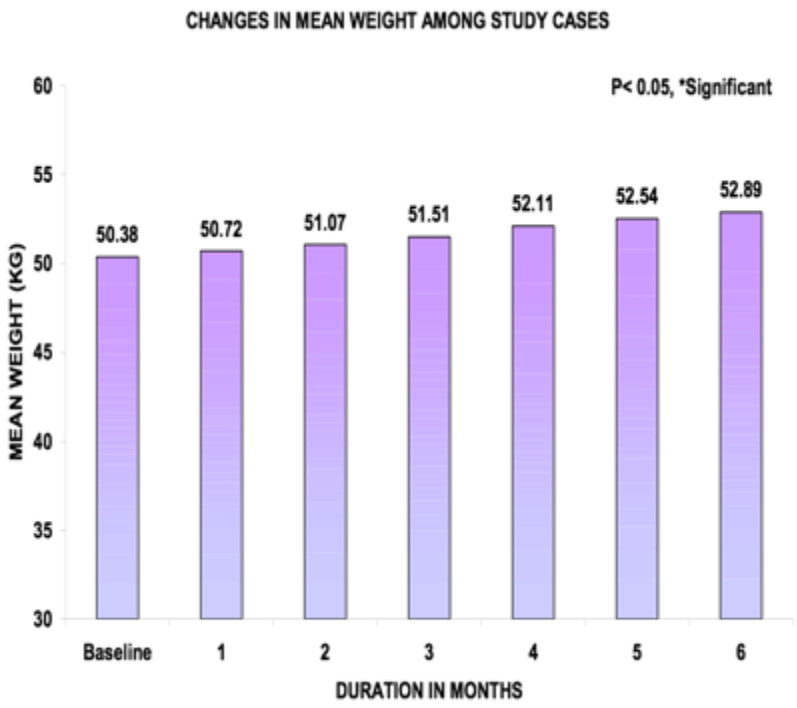


- **After 1 week of treatment with Radha 108 Nano Peptide, mean weight showed a significant rise of 0.7% from baseline.**
- **After 2 week of treatment with Radha 108 Nano Peptide, mean weight showed a significant rise of 1.4% from baseline.**

The same trend was observed from week 3 until the end of week 4.

Efficacy & Safety on HIV+ Patients in USA, India

Duration (Months)	Mean weight ($\bar{X}$ ± SD) (N = 5000)
Baseline	50.38 ± 09.89
1	50.72 ± 09.88
2	51.07 ± 09.82
3	51.51 ± 09.79
4	52.11 ± 09.75
5	52.54 ± 09.76
6	52.89 ± 09.77
Mean Diff. (Baseline – 1 month) (P value)	*00.34 ± 00.57 (0.001)
Mean Diff. (Baseline – 2 months) (P value)	*00.69 ± 00.91 (0.001)
Mean Diff. (Baseline – 3 months) (P value)	*01.13 ± 01.39 (0.001)
Mean Diff. (Baseline – 4 months) (P value)	*01.73 ± 01.71 (0.001)
Mean Diff. (Baseline – 5 months) (P value)	*02.16 ± 01.76 (0.001)
Mean Diff. (Baseline – 6 months) (P value)	*02.51 ± 02.07 (0.001)



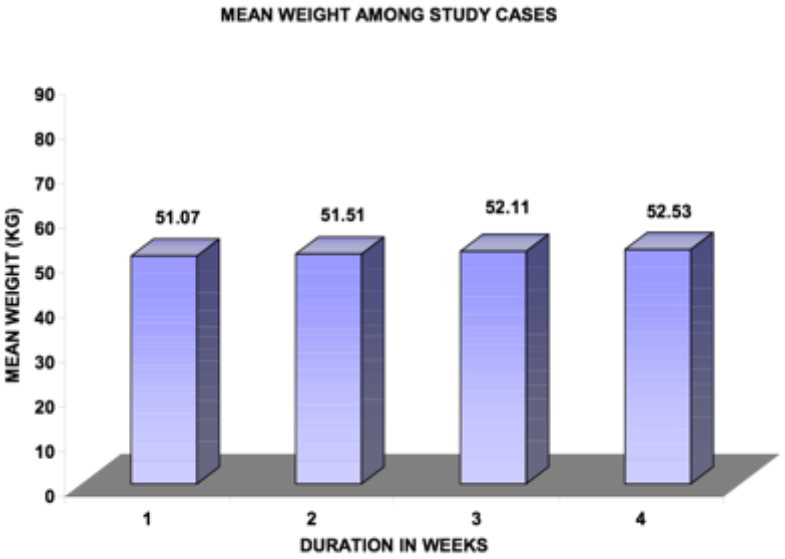
By ANOVA - Significant

- **After 1 month of treatment, mean weight showed a significant rise of 0.7% from baseline.**
- **After 2 months of treatment, mean weight showed a significant rise of 1.4% from baseline. A similar trend was observed up to the end of 6 Months.**

Efficacy & Safety Study on Swine Flu

CHANGES IN MEAN WEIGHT AMONG STUDY CASES

Duration (Weeks)	Mean weight ($\bar{X}$ ± SD) (N = 5000)
1	51.07 ± 9.82
2	*51.51 ± 9.79
3	*52.11 ± 9.75
4	*52.53 ± 9.76

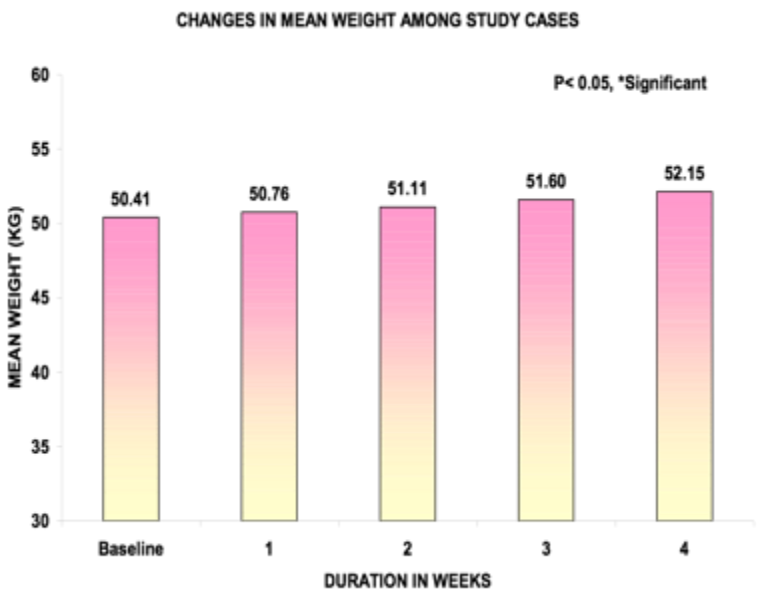


By ANOVA P < 0.05, * Significant

- **At the end of 2nd week, mean weight showed significant change from baseline i.e. mean change of 1.44 kg.**
- **At the end of 4th week, mean weight increased to1.46 kg from baseline.**

Efficacy & Safety Study on Allergy, Asthma, Arthritis, Diarrhoea, Fever, Fatigue-malaise, Anaemia & Endometriosis

Duration (Weeks)	Mean weight ($\bar{X}$ ± SD) (N = 5000)
Baseline	**50.41 ± 10.03**
1	50.76 ± 10.01
2	51.11 ± 09.94
3	51.60 ± 09.91
4	52.15 ± 09.91
Mean Diff. (Baseline – Wk1) (P value)	*00.35 ± 00.57 (0.001)
Mean Diff. (Baseline – Wk2) (P value)	*00.70 ± 01.05 (0.001)
Mean Diff. (Baseline – Wk3) (P value)	*01.19 ± 01.77 (0.001)
Mean Diff. (Baseline – Wk4) (P value)	*01.74 ± 01.95 (0.001)



By ANOVA *** Significant**

- **After 1 week of treatment, mean weight showed a significant rise of 0.7% from baseline.**
- **After 2 week of treatment, mean weight showed a significant rise of 1.4% from baseline. similar trend was observed up to the end of 4 weeks.**

RECEPTOL USP

Innovative & Affordable

Globally Patented

Broadspectrum Anti Viral

Immuno-modulator

Easy to Administer

No side effects (100% Natural

Can be consumed by all.. has no age or sex barrier, or drug - drug interaction

RECEPTOL THE DIFFERENTIATOR

Monoclonal antibodies

Checkpoint inhibitors

Cytokines

Treatment vaccines

Adoptive cell transfer

Bacillus Calmette-Guérin

Act directly against the cancer

Enhance the body's immune response to fight cancer

RECEPTOL Acts when All fail

Patent No – US 9,249,188 B2

Builds bodies own immune system.
Stimulates
Tumor Necrosis Factors
NK cells
Interleukin-1 to IL-11,
Interferon-α, INF–γ.

SWOT Analysis

Strengths	Opportunities
➢High Patented Brand Recognition ➢ Natural, no side effects ➢Entry Barrier via Global Patents ➢USP: No similar product ➢Strong marketing & distribution partners viz. Astra Zeneca, Abbotts, Dr Reddy, Lupin, J&J etc. ➢Multiple flavors in different formulations for all age groups	➢Viral Pandemics like Swine Flu, Rota virus and common cold. ➢Climate change leading to global warming resulting in a host of communicable and immunity disorders. ➢General awareness amongst masses of immunity booster nutritional supplements during breakfast lunch and dinner to prevent illness & provide good health. ➢The stressful life and time constraint may invoke working class to use it
Weaknesses	**Threats**
➢Entry of new brands with similar consumer perception.	➢ Nill

Sales Projections:

((	1st Half Year	2nd Half Year	3rd Half year	4th Half Year	5th Half Year
Target Patients	6,91,600	11,28,400	11,84,820	12,44,061	13,06,264
Projected Purchase 125ml Bottles	29,18,552	47,61,848	49,99,940	52,49,937	55,12,434
Total Revenue (in Million Rs)	1459	2380.5	2499.5	2624.5	2756

Assumptions

Segment Size	52,00,000
Definetly Buy	3,64,000
May Buy	25,48,000
Not Sure	17,16,000
May Not Buy	5,20,000
Definetly Not Buy	52,000

Assumptions

- 1st half: 50% of "definitely buy" + 20% of "may buy"
- 2nd half: 65% of "definitely buy" + 35% of "may buy"
- Subsequent growth of 5% in each half year
- Bottle purchase according to the usage pattern of "definitely buy" (8 bottles in half year) and "may buy" (2 bottles in half year)