

TIME TO REFORM



Product Front



Regulatory Front



Technology Front



Values Front

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02 Time to Reform – The Business Model

- Dr. R. B. Smarta

Having reached a critical juncture, managements of pharma industry are facing a number of questions and asks for crucial answers for the present and the future. There is an urgent need for a transformation in the industry practices as the industry has deviated considerably from its original path. How would the reforms and the choices of the leaders affect the pharma industry? Read on to get deeper insights.

On the
cover



08 Marketing Generics

- Interlink Knowledge Cell

Generic drug manufacturers and marketers have to face their fair share of challenges, right from high competition to quality issues. These challenges have to be met through a number of steps by Indian companies such as upgrading manufacturing facilities as per US FDA standards, hiring competent people and more. Our experts opine on these aspects to offer you some valuable perspectives & the steps to be taken.

Special
Feature



12 First Mover Advantage in an International Market;

A case-study

- Mr. Amit Dave

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Management
&
Markets



21 Urban Outlook for Nutraceuticals

- Interlink Knowledge Cell

The views urban Indians hold about healthcare are rapidly changing. The numerous health hazards are compelling the urban dwellers to turn to preventive methods. Some of the major segments that are growing steadily are those involving immunity, cardiovascular, diabetes, blood pressure and more. Gain a comprehensive outlook on the customer perceptions that are most commonly observed among the urban Indians today.

Thinking
Fresh

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FROM THE PUBLISHER'S DESK

'Time to turn'

It is time for the Pharma industry and the nutraceutical industry to take a turn and create a better sustaining business; a business that requires reforms right at the attitudinal level as well as operational level. Having reached a very critical juncture, the top managements in pharmaceutical industry have to make a choice and a better one for the future.

Every company has to choose its own path and look towards adapting a better business model, reforms in sales and marketing, R&D, clinical trials and focus on specific segments.

Those who would like to operate in generics market need to know more about how to market generics. Similarly, those who would like to concentrate on international markets need to choose their own path and make a sustainable difference in their approach for their own growth.

Besides strategic changes in terms of focus, companies need to shift towards different types of communication as well as build competencies in field force, so that, skills are developed and champions are moulded. This would enhance effectiveness as well as efficiency of every company.

In Nutrition and Nutraceuticals, it's obvious that at this moment, we have not captured the all India market but we have more metro markets, mini metro markets or urban markets. Even before we proceed to seize this opportunity, take a look at what the urban outlook is like today in India towards nutrition and nutraceuticals. How does the urban Indian feel about not falling sick. Has he already changed from 'Illness to Wellness'?

Hope these issues that every company is facing in Pharmaceuticals, Nutrition and Nutraceuticals get alternate thoughts that help in resolving them and moving forward in the right direction through a quick reading of this Interlink Insight.

Have a great reading! Looking forward to your response to this new structure of Interlink Insight.

Yours sincerely,

Dr. R. B. Smarta
Managing Director

Publisher – Dr. R. B. Smarta
Managing Editor – Ms. Ruth D'Souza
Editorial Team – Mrs. Mala Raj
Ms. Aarti Paradkar
Ms. Girija Dalvi
Mr. Raj Natekar

Interlink Marketing Consultancy Pvt. Ltd.
3A, Central Plaza, 166, C.S.T. Road, Kalina,
Santacruz (E), Mumbai – 400 098, India.
Tel: (022) 2666 6611 / 44
Email: info@interlinkconsultancy.com
Website: <http://www.interlinkconsultancy.com>



Time to Reform – The Business Model

- Dr. R. B. Smarta



Having reached a critical juncture, managements of pharma industry are facing a number of questions and asks for crucial answers for the present and the future. There is an urgent need for a transformation in the industry practices as the industry has deviated considerably from its original path. How would the reforms and the choices of the leaders affect the pharma industry? Read on to get deeper insights.

The Pharma Industry is now at a critical juncture even at inflection point and is facing multiple questions, each of great significance & relevance for its present and future.

The Pharma industry continues to remain an important industry, as the entire society depends on it for maintenance of health and for the treatment of all ailments – small and big. The industry which began with the motive of developing important, quality and safe drugs and selling them at reasonable and affordable prices has now deviated considerably from its original path. Hence it is important that the Pharma industry undergoes certain reforms with great urgency to save it from itself!

In order to restore this industry to its original path, it is important to see what has really happened and what is happening at this moment, so that, the choices which the industry needs to make, become abundantly clear. The pace of the reforms will depend on the choices made by the industry and its leaders.

Pharma Industry's 'Value-Migration' Model

The Pharma Industry has been considering the main purpose and executing its responsibility through the 'Value Migration' model. In this 'Value Migration' model, value was created through high investment in R&D to identify, select and carry out clinical trials and make it safer drug choice options for patients. This investment was in the processes and towards 'newness' of the new chemical entity. This new chemical entity was patented, so that, benefits could be accrued through these patents for longer terms like 15-16 years. Hence, value was created in laboratories, which then migrated to patients through prescribers or care givers. So, the need for mitigating new diseases as the environment changes as well as existing diseases was fulfilled by each product which is patented. However, very few countries in the world were following the patent regime with the majority 'developing' countries out of it. In

the Indian context, when we looked at this situation, it was a challenge for industry players as well as scientists in India who really worked on a slightly different model from the value migration model to get into the process of launching new products and mitigating the diseases. The Indian industry worked on 'Value Engineering' as well as 'Reverse Pharmacology' models. Through this model, big Indian pharma companies started getting into the process of manufacturing of even patented molecules, while the product patents continued to belong to those international companies who spent lot of money on R&D facilities. As a result, affordability of modern medicines improved in India. The industry, through its marketing and selling efforts, focused on the 'Prescribers' and through them, the patients. Both these models co-existed in India and also in the world.

Gradual Shift in Focus on Multi-dimensional Challenges

During the past 15 years or so, economic inflation, demographic change patterns and also blooming emerging markets have resulted in such a kind of environmental change that it has tilted the balance of patent model and process model to a very generic level. It came to a commoditized stage due to the population, paying power, disease burden and disease pattern. Emerging markets and near developed markets acquired a major source of income for industry to grow. India became an attractive country from all economic, demographic and also from the disease point of view. However, few factors have affected the industry to a great extent on different fronts:

1. Product front
2. Regulatory front
3. Technology front
4. Values front

On Product front, patents came up to a cliff and many of them expired, creating huge opportunities for generics. R&D cost went up so steeply that its viability started

posing a threat. Hence, outsourcing started proliferating. However, the entire process did not yield many new products.

On regulatory front, every country started viewing, with greater concern, the safety of medicines for their citizens. Affordability of medicines also became a factor of supreme importance. Hence, granting patents for new products as well as allowing new products to enter in any new country became very stringent and regulators started strictly monitoring it. The regulatory challenge was to harmonize the regulatory patterns all over the world to maintain the same standards of safety and quality. This became a big challenge for industry then and continues to be a challenge even now.

As a result of commoditization and markets becoming generic, the competition became so steep and intense that it affected the basic values of the industry at different levels, including at product levels, at the clinical trial level; at regulatory front, at permission level, sales and marketing level as well as at business level.

On the technology front, the new millennium shared a different kind of transformation in knowledge explosion with the expanded internet availability along with the boom in mobile phone usage. This technology also invaded the medical devices, instruments, pathology, radiology and many more areas resulting thereby in speedy and accurate diagnostics as well as product related benefits in the medical profession. This changed the perspective of medical profession which then began approaching diseases and their treatment in a more holistic manner resulting in a shift in the focus from only the 'drug' to other areas of diagnosis and treatment.

On the patient population front, there have been considerable changes in patients' demography, patients' use of technology for information of disease, treatment options, etc.

Patients are now well educated to discuss their concerns with the prescribers or

medical profession and also in a position to question the therapy suggested. It has posed a challenge to medical professionals

Due to intense competition **on the values front** the compromise which took place on the values based decisions has really corrupted the entire system of drug delivery at this moment and the entire system and industry are at cross roads. The industry is struggling to identify a new way to really go forward in the direction of the sales and marketing front.

Reforms in the Healthcare and Pharma Industries

The healthcare and pharmaceutical reforms have given rise to new opportunities as well as challenges. It is time to rethink about the way this industry has been functioning and to align the organizations with the reforms.

In the Healthcare industry there have been reforms like the launching of National Rural Health Mission (NHRM) by the government to bring about the correction in the basic healthcare delivery system. A systematic approach is adopted in order to implement this. The approach is related to the determinants like availability of nutrition, hygiene and safe drinking water for good health. This is essentially done through the mainstream of the Indian system of medicine to facilitate healthcare.

The Public Healthcare Foundation India (PHFI) addresses the limited institutional capacity by encouraging strong training, research and policy development in the area of public healthcare. In addition to this, the National Health Policy (NHP) has established firm goals like developing the competent technology for changing the healthcare delivery and making it efficient. Also, to spur private health insurance by increasing foreign investment is one of the major reforms in the healthcare industry. The healthcare reforms are putting pressure to reduce drug cost and to make the whole system evidence-based. These reforms have left no choice but to rethink over the ways to overcome the challenges faced.

The awareness about the strict regulated market and regulatory affairs have made it painful for the pharmaceutical companies. Besides, the patent expiries, Foreign Direct investment policies, Pricing Policies - with the price controls and rising taxes have made the profit margins ever shrinking. To add to it, the Compulsory Licensing and the enforcement of the marketing code in the pharmaceutical industry has left the current business model stagnant. Ensure, the above works, government intervention has increased like never before; also leading to the registration of the ethics committee and investigating sites and investigators. In addition, the delay in the approvals of the clinical trials has tangled the functioning of the pharmaceutical industry.

Why were these reforms inevitable?

These reforms have been a result of the findings of the assessment of the National Regulatory Authority (NRA) by the WHO in the years, 2001, 2004, 2007 and 2009. The findings declared lack of autonomy in the regulatory authority resulting in the inadequacy of the staff. This combines to result inadequate implementation of recall, review and quality systems. The most important point which came to notice was the unethical practices rising beyond limit.

The multiple choice question which is very important to respond is in fact a seven fold question:

1. Would the industry produce too many generic drugs and too few innovative drugs tomorrow?
2. Will regulatory become much too strict or it will be pragmatic enough to look at industry and also safety of patients.
3. Would the industry continue to maintain too much control over their clinical research or would they go ahead and extend their hand to regulatory compliance, pharmacoeconomics and pharmaco-vigilance?
4. Would the patent holders make adequate use of them, adopt

compulsory licensing or marketing rights or would they go ahead in the same way as they did earlier?

5. Would the industry continue to have lot of influence over medical education, medical professions about their own products or they would inculcate ethical practices in their own products?
6. Would the industry be transparent with regards to the ethics about its R&D, marketing and pricing?
7. Would the industry be too high, too viable or affordable?

These different questions would demand the industry make their choices.

Reforms come with Challenges and Rules: These reforms do provide significant opportunities; however, they also come with fierce challenges.

For the industry to sustain the growth rate and overcome the challenges, they will have to rethink the way they are doing the business. The various regulatory interventions need careful attention and consideration. To adjust to the regulatory environment and capitalize the opportunities, the industry will have to shift to a suitable business model. This calls for restructuring their processes. If the industry needs to tackle the challenges arising due to these reforms in a way that would add value, there are certain specific reforms essential to get the pharmaceutical industry back to its original mission.

Of course, there will be obstacles in doing so, but it will lead to this industry functioning as it claims to be doing. Few of the most important tasks that should be tackled and reforms to be brought in can include these.

Move from 'Me-too Drugs' to 'Innovative Drugs' – It is time for drug companies to focus on innovating new drugs to ensure better treatment and patient care. Examiners in the patent and trademark offices must understand and put in practice reforms that compel

'innovation' instead of 'copying'. This would also cut down on the huge marketing budget as a big part is spent on convincing the public how one 'Me-too' drug is better than the other. Generics or 'Me-Too drugs' would also need to find out ways of differentiation.

The need for FDA to be an independent & strong agency

– The regulatory authorities would have to go back to its 'regulating' approach from the 'facilitating' approach. FDA is crucial for public health and so it has to be well funded and patient needs have to be truly improved. Vital functions such as monitoring drug safety, inspecting manufacturing plants have taken a back seat because of the prescription Drug User Fee Act of 2007. It has been observed that the number of reviews done is directly proportional to the reach of FDA for the industry.

Clinical testing of Drugs to be supervised by the Institute

– Sufficient evidence points out that practices which are carried out bias the research to patronize the sponsor's drug. During clinical trials, strict supervision is needed so that it fulfils the medical need as drug companies tend to sponsor unnecessary studies for expanding their market. Also, it has to be ensured that the process be designed, conducted and reported with great care.

Restrict the Monopoly Marketing Rights

– For drug companies to have sufficient time to complete their clinical trials, monopoly marketing rights have to be curbed. A period of 20 years from the time the patent was filed is very long and has to be only about 5-6 years.

Raise the bar for better transparency and clarity

– The need of the hour is to be identical in practicing what the industry preaches as well as be transparent about what is practiced. They would have to be more open about their business practices as they cannot exploit the public anymore and also because they are dependent on the public for their functioning.

Pricing Structure – Furthermore, besides having a clear pricing structure, the prices have to be affordable and justified with emphasis. This is critical as the unsafe and unprotected people pay high prices due to the sort of discrepancies that exist. This unfair practice should be halted and there have to be regulations so that prices are made affordable to all. Since the government is the single largest purchaser of prescription drugs, they should carry out negotiations to regulate the prices on behalf of the public.

Sales and Marketing Practices

– Complying with code of ethics, there is a need of 're-skilling' sales and marketing business behaviour in tune with corporate objectives and the common good.

Patient's place in Pharmaceuticals

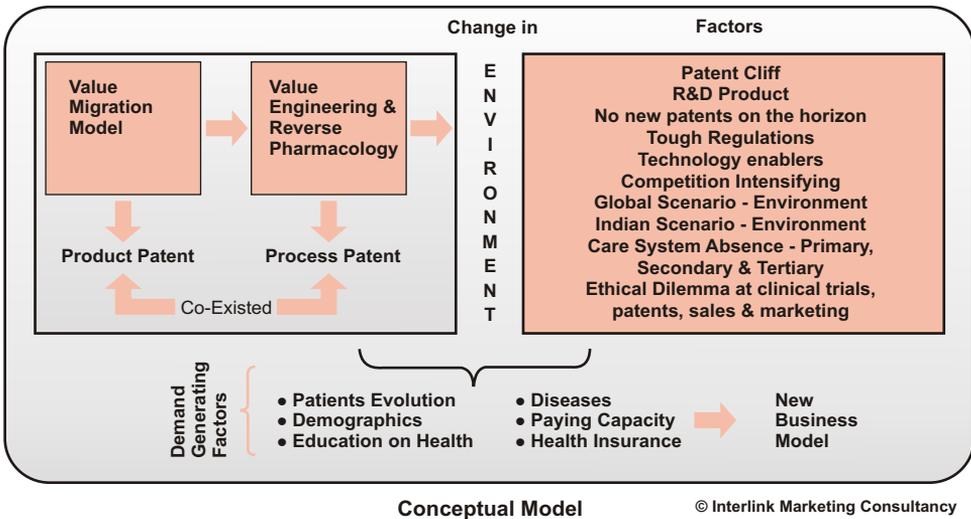
– There is a need for emphasis on the patient needs which have to be further identified and duly serviced. Perhaps, if it is imaginatively and skillfully done, companies may weave their business models around patients.

As the industry has shifted from its real mission and is spurred by the hunger for business, reforms will have to be proposed which bring the industry back onto the positive path. Thus, there is a need to establish a working business model that would continue to suit the changes as well as the evolving reforms.

New Paradigm

Obviously, looking at the issues and the kind of transformation needed, it would be evident that a shift of focus from medical professions to patients is likely to bring in a lot of change with respect to the business model or demand generation model in the pharma industry.

In case of patients, due to the evolution which has taken place in their perspective, perception, paying capacity along with education on health and diseases all over the world, patients are now a new transforming entity in every country. Therefore, the industry needs to deal with patient centricity in their business model.



Demand Drivers

Earlier the demand was driven by patented products and focus was on R&D investment. The process shifted to demand generation of process patents as the products became affordable and accessibility improved. As these demand drivers were the same, the generics industry started facing a problem.

Commoditization and earlier demand drivers virtually became ineffective. Having transformed patients, status of ethics and values in the industry practices affected the dealings of industry with the medical professionals. Patient started demanding much more focus so the industry could not understand how to really cope with their demand and how to deal with medical professionals in terms of balancing this business of medicines.

The new business model has to evolve slowly provided the major multiple choice questions are answered by the industry. These choices would reform the industry

at regulatory, clinical trials, testing, marketing rights and medical education level which deals with medical professional’s level and affordable and uniform pricing level for patients.

The existing way of doing business is not sustainable and it is understood by all the stakeholders. As a result, they would like to look for new ways to really sustain their business. Hence, the industry needs to discuss, develop, test, manufacture, distribute and promote medicines in a very different, ethically focused way for the benefit of fulfilling its existing and long term mission.

In case of developing a new model, it is important to look at how we have already moved from the core, as the core is becoming empty and ineffectual. It is time that the industry realizes that if it continues to travel on the same path, it would lead to high redundancy. This is the time when industry needs to move away from that core to creating new mini cores at periphery with continuous innovation.

Dr. R.B. Smarta, Founder & Managing Director of Interlink Marketing Consultancy, has more than 45 years of experience in the industry including over 28 years in management and business consulting. Being a thought leader, he has helped the management of number of organizations set up and grow through strategy consulting, sales and marketing effectiveness, organizational development interventions, successful mergers acquisitions and innovative video based training packages for Indian pharmaceutical and nutraceutical industries.



Marketing Generics

- Interlink Knowledge Cell



Generic drug manufacturers and marketers have to face their fair share of challenges, right from high competition to quality issues. These challenges have to be met through a number of steps by Indian companies such as upgrading manufacturing facilities as per US FDA standards, hiring competent people and more. Our experts opine on these aspects to offer you some valuable perspectives & the steps to be taken.

Indian pharmaceutical companies and their subsidiaries have successfully spread their presence in the global generic markets and have entrenched themselves in all the 3 types of markets, viz., matured generic markets (eg. USA, UK, Germany), early generics markets (Eg. Italy, Spain, France, Japan) & emerging generics markets (eg. Brazil, China, Turkey, Hungary). The Indian companies have received 178 Abbreviated New Drug Applications (ANDAs) approvals from US Food & Drug Administration (FDA) as compared to 144 in the previous year 2011 despite stringent approval norms. The US FDA granted a total of 476 ANDAs approvals during the year 2012 as against 431 approvals in the previous year. Of these total US FDA approvals, Indian companies grabbed 37.4 per cent approvals in 2012 as against 33.4 per cent in the last year.

The generic opportunity is not without its own share of challenges. High competition from local companies, competition from the innovator brand, low pricing, quality issues, shrinking profit margins and at times regulatory hassles are some of the main challenges faced by the generics industry.

To overcome these challenges, many generic manufacturers have adopted different strategies. Companies have used new technology platforms, new components and new configurations to provide better patient compliance and increase patient's quality of life. Super generics, biosimilars, bio-superiors, NDDS and value added formulations are some of the new product alternatives that have emerged. Thus, competition is being tackled with enhanced value proposition and product differentiation.

The pulse of Indian companies in this dynamic generics scenario was explored by Interlink Knowledge Cell which conducted a brief survey with 5 leading pharma experts for their opinion on the above. Findings of this exclusive survey are discussed below.

Markets Catered to

Indian companies are mainly catering generics in the regulated markets such as USA, UK and emerging markets such as Brazil, South Africa, China, Turkey, etc. Our experts opined that while registration in non-regulated markets is relatively simpler than in regulated markets. Each ANDA application does involve a lot of time, effort and expense for the applicant organisation to bear. So, in regulated markets the number of players is comparatively lesser than in un-regulated markets. The easier the registration process, the stronger is the level of generic competition.

The decision on which markets to enter ultimately rests with the organisation, based on resources available. Typically, the top 50 companies focus on regulated markets while the rest find it easier to enter the non-regulated markets.

Type of Products offered

Unanimously all the 5 experts concurred that India specialises mainly in offering the identical generic version of the original product, particularly of antibiotics, cardiovascular drugs, etc.

Developing a NDDS version of the original product is not 'everybody's cup of tea' as it requires a high degree of scientific competence from the R&D team. Offering generics that are difficult to develop (eg. Patches, Pulmonary devices, special topical forms, etc) are not common for Indian companies. A few top Indian companies are working on biosimilars.

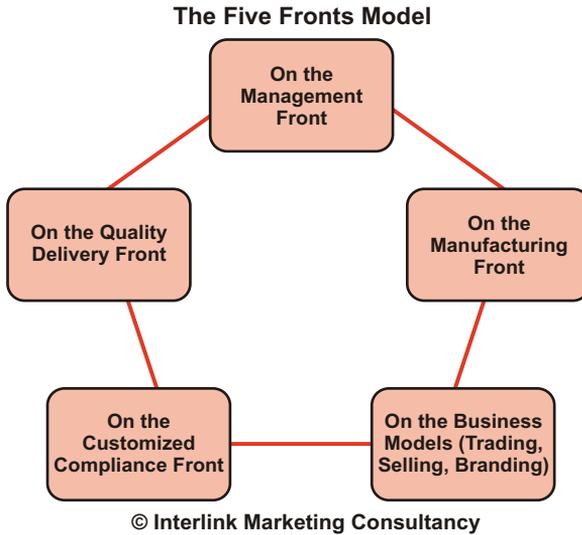
Challenges faced in Generic Marketing

The most important challenges in generic marketing were the tough competition from the innovator brand followed by the low pricing and low margins. Competition from other brands was not rated as a major challenge. As regards regulations, experts cited that, 'getting approvals from the regulatory bodies' is also a difficult issue that they face, particularly in the regulated markets and in China. Other challenges

faced include patent battles with the innovator brand with its long drawn legal proceedings and at times, rejection due to quality issues.

Steps to take for meeting these challenges

Indian companies are taking multiple steps towards tackling these challenges. These steps are on the following fronts; management mindset from average volume, high margin to above average volume and meagre volume where quantum of margin would be higher.



Upgrading Manufacturing plants to standards of US FDA, upgrading the registration department and documentation processes, hiring / training competent people in these areas, implementing strict QA / QC norms are some of the important steps that organizations can take. Conduct BE / BA studies for all exported generics.

One of our experts also felt that the industry must take onus of ensuring quality checks periodically of exported generics from the country, by creating a new independent monitoring mechanism.

Difficulties faced when implementing these solutions

While the top companies have adequate financial resources to implement the above

mentioned steps, the smaller Indian companies face this constraint and do get caught up in a difficult situation. The entire industry gets a bad image if the quality of even a few Indian-made generics is poor. Monitoring the quality is a major issue. In developing countries, the government is often the major purchaser due to shrinking availability of funds for healthcare and due to ageing population. Getting orders from these Governments is getting very difficult.

In conclusion, Indian companies do have a challenging time in choosing the path ahead for their generic business, particularly with regards to the markets they choose and the resources they can make available to enter the more mature western markets.

Interlink Knowledge Cell comprises of a team of experienced subject matter experts in various domains like Pharma, Nutra, Biotech, Animal Health and Wellness, to provide insights and business perspectives. This was a round table story on Generics taking into account valuable opinions of our experts. (Our experts interviewed for the Round Table Story are Mr. Uday Karnik, Dr Arun Bhatt, Mr. K. Chandrasekharan, Mr. Suniel Deshpande and Mr. Ashok Turki who are all Senior Consultants with Interlink)



First Mover Advantage in an International Market; A Case-study

- Mr. Amit Dave

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First Mover Advantage in an International Market; A Case-study

- Mr. Amit Dave

The case-study provides treasurable acumen about what goes on when a new drug is launched in an international market. This case-study which is based on an actual launch showcases all the steps and other intricacies that go on to make the launch a successful one. It offers a phase by phase glimpse of the strategies employed.

This case study is based on an actual launch*, though the names are changed. All the situations have actually happened in the market.

The situation

Uzbekistan was part of USSR before 1991. However, after Glasnost and Perestroika, when all the parts of the Russian Federation separated, this double land locked country, which now has a population of about 30 million, was left without any respectable industry.

Rich gold, uranium and natural gas resources, along with very good agricultural yield of high quality cotton, made the country self-reliant in the economy. However, for medicines, the country still depended on grey market supplies from Ukraine, Belorussia and Russia. Except one Korean pharma manufacturer based in the city of Syrdarya, the country had no pharma manufacturing base. Even for low end critical products like I. V. Fluids, the country largely depended on in-house manufacturing by the hospitals which, in a way, were with primitive kind of facilities.

Why did the country not attract good manufacturing? First, the size of the country at that time was too small. Secondly, closed economy, governed by a dictator who was a qualified economist himself, did not allow or attract foreign investments due to controls on repatriation.

Pharma market

Currently, the size of pharma market is about USD 500 million in Uzbekistan. Though

small, for a population of 30 million, the marketing environment with practically zero competition made this market interesting.

There were many good distributors and pharmacies (Aptekas, the name derived since the USSR time) in the market. Many new launches were tried but failure rate was high because of reasons not well understood.

The market followed the pattern of India, with Antibiotics and Analgesics making the largest percentage.

DPL (name changed), one of the large I. V. Fluid manufacturers of India, was supplying I. V. Fluids to Uzbekistan, and during one of his visits, the MD of this company saw a big opportunity for pharma products in Uzbekistan. The company had a small Pharma Division, called DLL but pharma was not the major strength of the company. As a special case, the products were sourced from a contract manufacturer through a supplier and dossiers were submitted for registration through a subsidiary in Uzbekistan which was involved in I. V. Fluids importation. Registrations were obtained in six months. The first product which was approved was Dorflam (based on Combiflam and taking D from DPL), a combination of Ibuprofen with Paracetamol. Though an old product for India, for this country, it was a novelty in the last decade.

The First Launch

This was done with some good publicity. All the Government hospital doctors were invited in their respective hospital auditoriums and a small lecture on the product was given, followed by lunch / snacks. The product was well received and

doctors gave commitments of prescription. This whole project was managed by the I. V. Fluid team since this was the team residing in Uzbekistan. Some quantity was imported and distributed. Some initial sale had happened but soon the sale saw a plateau. On the other side, a large quantity was imported by the company which, if not sold, would have to see expiry, though the shelf life was of three years.

After accessing the overall situation, the MD of the company made a small team of three Pharma product managers and sent the team to Uzbekistan.

Market and situation analysis

The team leader hired a doctor, Dr. Timur, (Taimur, the famous warrior of history, was from Uzbekistan - known as Timur locally, and this name is quite popular there) an old man, with very good English communication. The first three days were spent in a hospital, a large pharmacy and a distributor respectively where Dr. Timur would translate the smallest details communicated and other members would make notes. On the third day, half of the day was spent in the street meeting old people and asking some questions.

“Let us empty our minds totally and just observe, without conclusions”, the leader shouted. The people were extremely cooperative since India enjoys very good popularity in this country.

The observations were compiled and the situation analysis was as below-

1. There was no existence of GPs or private clinics in Uzbekistan because of the old socialistic pattern of USSR. If a patient suffers from headache, he is supposed to visit a hospital, enter his name in a waiting list register, wait for the attendant to give him an appointment time, and then come back at that time, unless there is an emergency. Headache, of course, was never considered an emergency.
2. India had considerable brand equity, due to the history of Mughal dynasty

(which had originated from Uzbekistan). The word “Hindustan” provoked great respect. Bollywood heroes were quite popular too, including Raj Kapoor, Mithun Chakraborty and Salman Khan.

3. Salary of pharmacists was very low. Sometimes, it was as little as 20 USD per month. The same was the earnings of many qualified people at the starting stage, having no experience at all, including women.
4. Local TV was not very popular though international channels were popular. Local radio, on the other side, relaying European music, was quite popular.
5. Russian products were being used for generations and so, had high level of trust, though no new medicines were coming from Russia.
6. When asked “What will you do in case you do not get a doctor’s appointment fast for pain?”, the answer was “we consult Pharmacist.”
7. When some pharmacists were asked about how they will recommend a product to a patient, their response was typical. If they suggest wrong or mild medicine, the patient will avoid coming to the store next time, and may tell the owner sometimes that the pharmacists suggested some wrong medicine. They would, therefore, be very conservative about the recommendations.
8. Level of primary education was very high because of the old Russian system. All the people including women were literate and involved in decision making.

Phase II launch

Based on the above mentioned observations, the team made salient features of the strategy as below –

- Involvement of pharmacist
- Attractive packing
- Radio advertisements
- Massive one time launch with demonstration

It was also found that the tablet had disintegration time of 30 seconds. This was not by design but since the product was the copy of an Indian formulation, it had come as a default since in India, the product had this feature.

Immediately an outer box was designed. All costly products in the country had a secondary pack, like an outer box. This box had a picture of an elephant with the words “Powerful yet Gentle”, besides the product name and legal information.

A team of 10 ladies was prepared. Each lady had to camp in one store everyday, demonstrate faster disintegration to all the pharmacists, and all the patients coming to the store, and in the evening, take a small order for the product. They were hired for two months and covered 400 stores and 1000 pharmacists. A small radio advertisement highlighting “Powerful yet Gentle” theme was relayed for one month. Cost of hiring 10 ladies and advertisement

were low comparatively due to high number of educated people available.

The results were dramatic. After two months, the sale picked up to 5,000 packs, and winter season which was to follow in another two months raised the sale to 15,000 packs per month, each with two strips. In value terms, this came to almost USD 100,000 per month making the brand of USD 1 million in this small country.

Subsequent launches, one of an antispasmodic combination and one of an antibiotic, followed the same patterns and the same success rates.

In the second year, the major strategy was-Distributor channel expansion (from 12 to 37) and patient demos inside public hospitals on the lines of pharmacy demos.

In the third year, the product was shifted to OTC profile with displays of inflated elephant at public places symbolizing the product, etc. Performance of the product was spectacular with these initiatives.

Points of discussion

1. The most critical factor for success was market survey and study of the market dynamics. Typically a company tends to believe that the dynamics of India will work in other markets also, but this may not always be true. Doctors were already involved and so, in many cases, when the patients asked the doctors their opinion on this medicine, doctors also supported the product. In other words, though medical promotion had helped, the critical success factor was a semi – OTC like treatment including radio advertisements and involvement of a pharmacist, special packing, and so on.
2. With no new launches in the market, there was a good opportunity in the country. Direct action at stores with qualified people at a low hiring cost, unlike medical representatives, clicked. This not only involved the patients and pharmacists, but even store owners.

(Subsequently, one plane was hired and all the major distributors were taken to visit the I.V. Fluid plant of the company in India. They were shown the I. V. Fluid plant. This visit helped prevent entry of illegal medicines coming from the old Russian block and enabled good rapport building with the distributors, which also helped in future launches.)
3. Local subsidiary helped the company overcome financial controls which affected other companies adversely. Local infrastructure wherever appropriate, helps a lot in the international markets.

(* This is an actual case study of a Brand launched by an Indian Pharma company in Uzbekistan in the last decade with strategic support from Interlink Marketing Consultancy. Dr. Smarta & Mr Amit Dave have personally worked on this project.)

Mr. Amit Dave is currently working with Zydus Cadila as Vice President with focus on LA business development. In the past, he was heading International Strategy function in a large healthcare company and has had a good exposure to practically all the international markets. The product range handled by him includes high end hospital products, generics and specialty Branded products. His major experience is with Brazil for both Generic and Branded business.

Emerging Scope of Communication with Patients

- Mrs. Mala Raj

The Indian patients in rural as well as urban areas are continuously evolving. Patients are now empowered by access to education and awareness campaigns at different levels. Know more about the strategies to be employed, how one can bring about innovation in the pharma communication and the benefits it offers since the average Indian would soon want to take independent decisions about their health and healthcare.

The Indian consumers and patients are continually and rapidly evolving in urban areas & gradually in rural areas. Access to education and health awareness campaigns carried out at various levels have enabled in empowering the Indian patient.

We have four categories of patients – In urban India and class I towns, the internet has changed patients' outlook, particularly among the educated class of citizens. At the top, we have the elite and educated group, who, rather than approach the Dr with the symptoms, approach the Dr with adequate information on possible diagnosis of his symptoms and await the confirmation of his diagnosis from his Dr!

In the next category, we have patients who are eager to know more about their condition but are confused by the immense volumes of information that they find over the internet.

Then, there is a category of 'ignorance is bliss' variety of people, who neither have the inclination to learn more on health issues nor consider it essential.

The last category feels there is nothing wrong with them and nothing can go wrong with them. They awaken to an unpleasant shock only when they face some health disturbances.

Reaching out to all these diverse categories of patients with communication strategies at the moment is very challenging a task. So the vast majority of 'eager to learn more' category of Indians from the 2nd category can be focused on for generalised communication while

separate communication mode can be developed for other categories.

From the regulatory point of view in India, pharma companies can educate patients on the conditions, symptoms, diagnostics areas but can not suggest or recommend any products. That is the domain of medical professionals.

How are we communicating?

The Pharma industry cannot, as per our governing legal rules and regulations directly address or reach out to patients with any communication on their ethical products. Yet, it is of strategic importance to reach out to the vast Indian customers with clear communication strategies that will enable companies to build a better corporate image and identity. Patient education on the disease, diagnosis, prevention and care of the same will be welcomed as a measure to improve health awareness of the country and its citizens. Many pharma companies have used this strategy to create a distinct image for themselves in the therapeutic areas where they offer products, by spreading simple and important messages on the underlying medical conditions. For example, Cipla's campaigns on Asthma care, GSK's campaigns on Chicken pox & 'Anti-tobacco – Quit Smoking' campaign.

Patients often have a lot of queries on their disease condition, its severity, its progress in future, its complications, etc. Many of these questions often remain unanswered as the Doctor is either too busy to address all such questions or because the patient himself feels inhibited to raise such

questions considering the busy schedule of his Doctor. Pharma companies can address this area through promotional strategies that involve both the Doctor & his patients.

Is it time for India to follow the DTCA steps?

Direct-to-consumer advertising (DTCA) is one of the methods of marketing pharmaceutical products by reaching consumers directly through various advertisements. So far, only 2 countries, viz, the United States of America and New Zealand permit DTC advertising of ethical medicines. The prime focus of this method is to improve the consumer's knowledge on diseases and treatments and to encourage them visit their primary physician to discuss health related issues.

The advantage of DTC advertising is that it informs patients of various diseases, treatment options including new options. It meets the demand for medical information, which is an inherent unaddressed need of all consumers and patients. It encourages patients to seek medical advice and makes them proactive in health related issues. At the same time, DTCA also suffers from a few disadvantages, which must be kept in mind. DTCA increases the risk of 'patient miscommunication'. It can, in certain individuals, lead to self-diagnosis, flawed diagnosis, imagined illnesses. Besides the consumers, it can also affect the Physicians adversely, as there can be increased pressure on the physician to recommend a particular product.

DTC in India

In case of India, using DTC advertising for the promotion of prescription allopathic drugs is not permitted. DTC product promotion is prohibited for Schedule H and Schedule X drugs. In India, direct to consumer (DTC) promotion is used in the sphere of social marketing, for eg., on family planning initiatives, on vaccination, on hygiene, sanitation and disease awareness. DTC product promotion is permitted for AYUSH formulations, viz., Ayurvedic

proprietary medicines, Unani, Siddha & homeopathy drugs. It has also been used for OTC medications and for certain treatment categories such as inhalers for Asthma, contraceptive pills, insulin for diabetes, etc.

How to progress?

Communication to patients can be routed through the Dr and through the DTC options available for spread of information. Companies must combine the power of in-clinic communication with mass media like health columns in newspapers, in health magazines and mass reach media like the Internet. Among the earliest mass reach programs in the country included the street shows for awareness building and detection camps by many pharma companies for hypertension, diabetes, osteoporosis, asthma, etc. In the past decade, patient information leaflets / booklets in multi-languages and patient information charts grew very popular. In today's digital era, these efforts can be supplemented with dedicated websites on disease conditions with simple and lucid information, that too, in local languages, to reach out to patients across the length and breadth of the country. Having help-lines for diseases and patient queries is also a good option. Companies are also experimenting with creating websites for Doctors to address communication needs of his patients.

Companies can also exploit the social media for connecting with their patients, particularly if they have OTC healthcare brands. A recent study from PWC's Health Research Institute has established that 40 per cent of consumers have used social media to find health-related brand reviews. With 400 million Facebook users in the country, Facebook can be an important tool for viral marketing for OTC healthcare brands. Companies with ethical brands too can use the social media to create an image for themselves in chosen areas of relevance.

The humble product pack, itself can serve as a valuable media for reaching the right patients. Inclusion of well designed

‘Patient education leaflets’ with simple Do’s & Don’ts is a simple strategy that the industry has overlooked for many years now. Asking the patient to visit the website to gain further information is a pull strategy that works very well. Inclusion of QR codes that draws the patient to the corporate website or disease-specific website hosted by the company is also a simple and smart way to reach the smart phone wielding class of patients.

But will this scenario change? Will DTCA reach Indian drug industry soon?

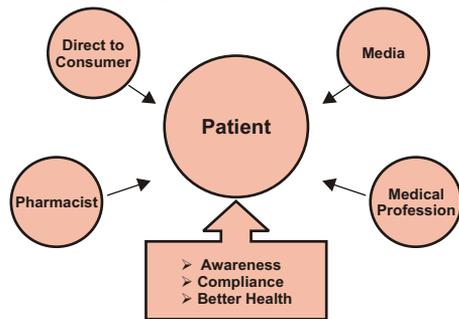
The current marketing environment is witnessing many changes. The world is moving towards one open society; the healthcare attitudes of consumers are changing; at the click of the mouse consumers have quick access to world class information through the digital & internet revolution; there is greater patient empowerment, and there is close integration of Indian medical sector with the global medical sector. Due to free access to Internet, every search for any medical condition or medication is accompanied by direct and indirect reference to brand names of drugs or even advertisements of International drugs. Thus, indirectly, the educated net-savvy consumers in India are already being exposed to DTCA for drugs.

However, the vast majority of Indian masses are far from having even a basic understanding or awareness of health issues. The legal restrictions make it difficult to reach the mass. Perhaps, at a future date, the legal restriction may undergo a change. But still, there are a few concerns that will have to be addressed before using DTC advertising in India. Regulation of DTCA is very important to have a balance between the benefits and disadvantages of DTCA. Alongside having the right norms and rules in place through government bodies, it is also important for the industry to have an approach of self-regulation. Making the right claims, stating the requisite risk factors and presenting the right communication for

the large illiterate population of the country, are factors to be borne in mind.

On the positive side, DTC advertising would keep a check on the unethical medical prescribing done by doctors who take advantage of their patient’s ignorance. DTCA will create a new generation of informed consumers / patients and will be a step towards creating a healthier India.

Effectiveness of Patient Communication Strategies



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In generic era, it is important to provide value to customers and patients besides medical professionals. As we observe, in many ways lifestyle diseases, ‘drop out’ of patients is increasing. On the other hand, if you follow the method of communication to customers and patients you would find better compliance from patients. Effectiveness of communication can be well plotted. It can increase the offtake.

As this is a new means, pilot testing needs to be conducted and cost – effectiveness needs to be worked out. There is no doubt that, in the long run, such campaigns do have a positive influence on the company’s image and the image of its brands.

In years to come the average Indian is going to be taking more and more decisions on health and healthcare by himself. The focus is already shifting from disease treatment to disease prevention in urban India. Occupying a slot in the minds of this category of ‘Health Conscious Indians’ is a strategic option that Pharma companies must invest in. Do you have such a strategy in place?

Mrs. Mala Raj, is a senior consultant at Interlink. She is a brand management expert and is well versed with the intricacies of Pharma Marketing in the country. She is an excellent trainer for marketing strategies and selling skills for MR's.

Raising Market Based Competencies of Sales Force

- Mr. Vikas Divekar

For every pharma company to grow and succeed, having a competent sales force is of great importance. If every medical representative possesses the right skill set complemented with the right knowledge and attributes then the organization's sales force can surely bring in the desired sales results for them. Perspectives and alternatives to the looming question of how the management can ensure that the sales team has the right skill sets through different interventions are elaborated.

Competency is basically the skills which when combined with knowledge, behaviour and attributes can result in high performance. Competencies take into account how the work is done. It is a well known fact in the best companies that competency enables results. Consistent good results are achieved by increased proficiency in work and exhibiting the right competencies.

More often than not, behaviours and attributes are innately present in an aspiring salesperson while knowledge and skills can be acquired through hard-work. In a highly competitive market like pharmaceuticals, having a high performance sales force is no less than a formidable weapon. So, it is important that every medical representative should have the right competencies to be a valuable asset to the organization.

A Medical Representative (MR) is still an important element for a pharmaceutical company to succeed. The success of any company to a great extent depends on how effective their medical representative is to generate prescriptions. For this, an MR has to have a wide skill set. This is because he plays the role of a brand ambassador and also a crucial link between the organization and the medical profession.

A medical representative is a professional and it is in the scope of his work to keep doctors updated with current developments in the field of medicine that build confidence in MRs ability to promote the company's products and generate prescriptions.

Some medical representatives have well-developed skills while others need to acquire them through training. Given today's scenario, at entry level, training and developing MRs is all the more critical.

Pre-requisites – An MR has to be equipped with a knowledge skill set such as

Knowledge Requirements of an MR
Product Knowledge
Competition
Customers
Territory
Latest Development in the field of Medicine

- **Product Knowledge** – It is vital that an MR should know everything about his product.
- **Competition** – An MR has to know more about the competition as much as his competitor knows about his product and claims, including promotion activity and prescribers.
- **Customers** – He has to have the complete know-how about his customers, be it their needs, prescription habits, preferences, demographics, etc.
- **Territory** – The MR has to know his territory, total market opportunities, etc.
- **Latest Development in the field of Medicine** – An MR has to keep himself updated with the latest technologies as well as the regulations in the field of medicine, especially in represented therapy areas.

Skills – In addition, it is critical to have the skills to utilize the knowledge acquired and communicate effectively with the customers to better the performance.

Skills Requirements of an MR
Communication
Grabbing Attention and Retaining It
Objection Handling
Collecting Competitors' Information
Demanding Prescriptions
Identifying Customer Needs
Collecting Information from Retailers
Identifying Gap between Opportunity & Actual Business
Post-call Analysis

Onus of developing skills –

Having deliberated on skills required and means to develop them, we now address the critical issue of, who in the organization must take responsibility of developing the skill sets of their field force and how should they go about it.

It is here that the role of the management is critical. Many organizations fail to achieve their performance targets as they are unable to link the skills of their employees to the corporate strategy. A competency-based skills management system must be created to ensure that all employees develop the skills required to achieve the corporate goals. A suggested checklist for the same is outlined below:

- Identify the skills and tasks most critical at each level to succeed
- For each skill, identify the minimum performance standard for each level
- Assess objectively, the level of each field force member for the identified skill areas
- Compute the gap between the expected & existing skill levels for each field force member for each skill set

- For each skill determine what training exists or should be created to develop these skills proficiently
- Involve employees in the process by developing a personalized learning plan and equip them to self-assess their progress in skill acquisition
- Allocate adequate resources - in terms of training effort, time of the superior available to the junior and the training budget, for developing the employees
- Regularly monitor the progress & repeat the process periodically, as the required skill sets keep changing with changing organizational goals.

In conclusion, building competency in the sales team is an asset that every organization must strive to acquire and constantly build upon.

How to develop these skills?

Some MRs have well developed skills through experience. But others have to develop skills through training and practice.

One way to surpass competition and gain respect from medical professionals is by developing a competitive edge over others. Four factors that can help and develop medical representative are:

Active Observation – A medical representative can gain great insights by being very observant when on the job.

Learning through experience – In the field, an MR is able to assimilate important information about his customers, competition, market and in the process learn.

Reading – Reading is a good habit an MR should inculcate for his effectiveness and success.

Practice – A training program and seminar go a long way in improving the skills of medical representatives. This needs to be practiced constantly and implemented in day to day working.

Identifying skill gaps and developing them with consistency

Acquiring a skill set can ensure satisfying results for the medical representative and increased sales for the organization. A company can draw benefits when they acquire the right talent or train their MRs. By making use of his skills, every call can be effective in generating prescriptions.

As a professional, an MR has to generate maximum business from his territory by reducing the gap between the potential and actual prescriptions. This will help an MR achieve the sales objectives and increase the market share. Furthermore, if an MR can create a good impression on the doctors, more often than not it helps to

build a positive image of the organization resulting in intangible benefits.

With an increase in the sales, a medical representative can grow in his career as well as augment his remuneration. This will help motivate the MR further to put in better efforts. A good skill set also helps an MR such that he is inspired to get the much needed job satisfaction, at the same time reduce attrition.

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Mr. Vikas Divekar has an experience of more than 40 years in Pharmaceuticals – Sales & Marketing. He has effectively handled various functions in multinational pharma companies - involving both – pharmaceuticals as well as OTC healthcare products, pharmaceuticals as well as OTC products. Now, he is holding a position of Senior Consultant in Interlink.



Urban Outlook for Nutraceuticals

- Interlink Knowledge Cell



The views urban Indians hold about healthcare are rapidly changing. The numerous health hazards are compelling the urban dwellers to turn to preventive methods. Some of the major segments that are growing steadily are those involving immunity, cardiovascular, diabetes, blood pressure and more. Gain a comprehensive outlook on the customer perceptions that are most commonly observed among the urban Indians today.

India is now one of the emerging markets with an increasing demand for nutraceuticals and dietary supplements. The burgeoning affluent middle class population in the country is increasingly becoming health conscious. This is especially true in the case of urban Indians with the increasing awareness of health issue, increasing numbers of health awareness camps and seminars conducted in the cities and with the growing need to remain active and disease free all 365 days of the year. We, at Interlink, besides secondary research on this topic, also explored the reality with regard to this shift by conducting a brief primary research survey of 35 respondents in Mumbai city

during the months of April & May 2013.

Target Group: Total Number = 35

- Males & Females (All Adults)
- Metro City (Mumbai)
- Age Group - 25 years to 85 years
- Males - Service or Business men
- Females - Working & Housewives (married & Unmarried)

Emerging Breed of Health Conscious Urbanites:

Urban Indians are acutely aware of the health hazards that they are exposed to in their everyday life and are no longer content with inaction to ward off its consequences.

Health hazards that people are exposed to...



Figure 1: Health Hazards

City dwellers today are afraid to fall sick as the hectic city life is difficult to keep pace with. Urban Indians face tremendous stress and there is high incidence of lifestyle diseases such as cardio-vascular, diabetes, blood pressure, anxiety, depression and more.

Even the normal ageing process has become a daunting challenge to many. The growing nuclear family way of life leaves most elderly couples alone in their golden years, without their grown-up children

nearby to tend to them. This makes them take a more serious view of the matter.

Outlook to ‘Health, Disease & Ageing’:

An overwhelming majority of urban Indians are health conscious with 82.9% of respondents agreeing that, ‘**Prevention is better than cure**’, for which they do take preventive measures. The busy life-style of urbanites perhaps does not even permit them adequate time to recover in case they fall sick! Hence a preventive approach finds good favour among this group.

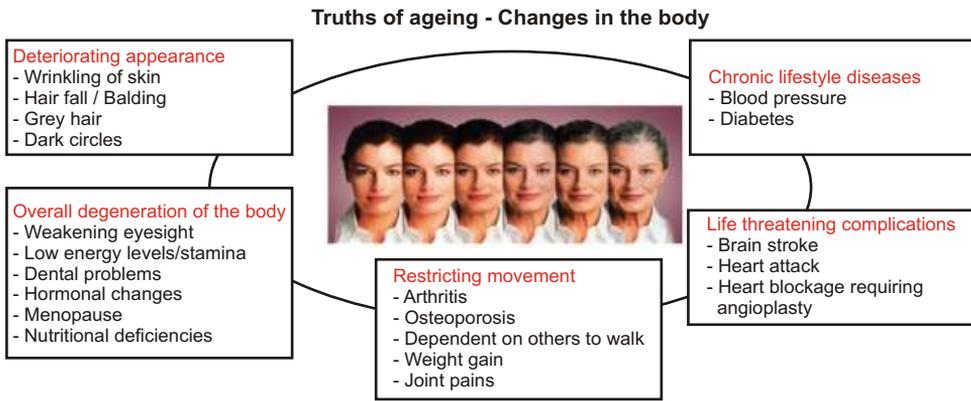


Figure 2: Changes in the body

Some of their key unmet needs include the following

- Remain attractive and beautiful for self/partner
- Look young and remain active
- Desire to be healthy
- Continue to be independent
- Enjoy things that have been missed earlier in life / pursue interests and hobbies
- Spend quality time with family

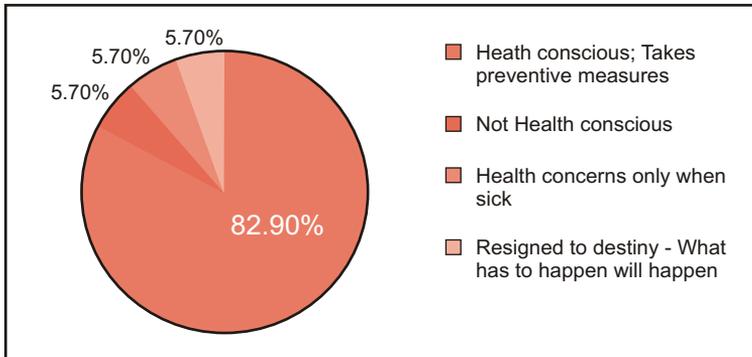


Figure 3: Approach to Health among Urban Indians

Current activities/products directed towards health and beauty:

Urban Indians can incorporate beneficial habits such as diet control with maintaining a balanced diet and drinking lots of water, exercising regularly, lifestyle changes such as adequate sleep and more, consumption of health supplements such as chyawanprash, home remedies, etc. in their daily routine. Thus, this way urban Indian can keep himself/ herself healthy in mind and body. Among these, the focus of our study was on awareness and use of Nutraceuticals.

Truths on ‘Nutraceuticals’: Key findings

- 85.7% are aware of Nutraceuticals
- Nearly 50% of respondents use health supplements occasionally or regularly – as preventive measure against sickness.
- Among the various supplements, Chyawanprash type Ayurvedic product and Vitamin combinations favour greater acceptance.
- Some of the brands used regularly included Dabur, Sonachandi and Baidyanath chyawanprash, etc.
- Fruit juice is widely accepted by Urban Indians with 100% of respondents using the same regularly or occasionally.

- While Energy drinks are consumed more often occasionally, the probiotic drinks have poor acceptance with no regular consumers of the same.
- Improving 'Immunity' was cited as the most important reason for consumption of nutritional supplements.
- Other areas of concern include digestive health, body weight issues, cardiovascular health and remaining overall fit.
- Though the 'Retail Chemist Shop' remains the preferred outlet from where nutraceutical supplements are purchased by the consumers, a good number of consumers regularly purchase the same from 'Super markets' or even their local 'Grocer shop'.
- The key influencer remains the Doctor.
- 'Word of Mouth' (WOM) suggestion / persuasion by a close family member or friend who has experienced gains from using the product is also a major influencer.
- On an average, the monthly family expenditure on Nutraceutical products in urban India is around Rs 500 to Rs 1000. However, a good 34% spend more than Rs 1000 per month on such preparations.

Pointers for 'Nutraceuticals' Marketers

Urban Indians believe in the mantra 'prevention is better than cure' and so are willing to spend on preventive methods of treatment. With the increase in the disposable income of the people, they do not shy away from spending more on preventive healthcare methods to stay healthy and fit. One good example of this

Interlink Knowledge Cell comprises of a team of experienced subject matter experts in various domains like Pharma, Nutra, Biotech, Animal Health and Wellness, to provide insights and business perspectives focused on Management, Marketing & Training areas.

would be sports medicine centres where numerous athletes get their complete treatment under one roof ranging from their diet plans to rehabilitation from an injury.

In a similar way, there is a rise in the wellness centres and stores being introduced in big cities where these centres not only provide nutraceutical products but also offer consultation about which product would suit their needs and diet, etc. Chemists and super markets are not the only place where these products are available.

Another major change in the outlook of urban Indian's today is towards natural remedies. People are now more open to other therapies such as Ayurveda, herbal remedies, etc. It should not come as a surprise that city-dwellers want to have better immunity as their daily life exposes them to many factors that predispose them to ill-health such as increasing pollution, faulty eating habits, etc.

Other segments that are very popular among urban Indians, besides immunity are digestive health, weight issues, cardiovascular health, joint and bone health, eye care, oral health, skin and hair care.

There are still a large number (nearly 50%) of urban Indians who do not wish to take nutraceutical products. These individuals should be made aware of how important it is to conserve good health from a young age instead of waiting till there is a dire need for it.

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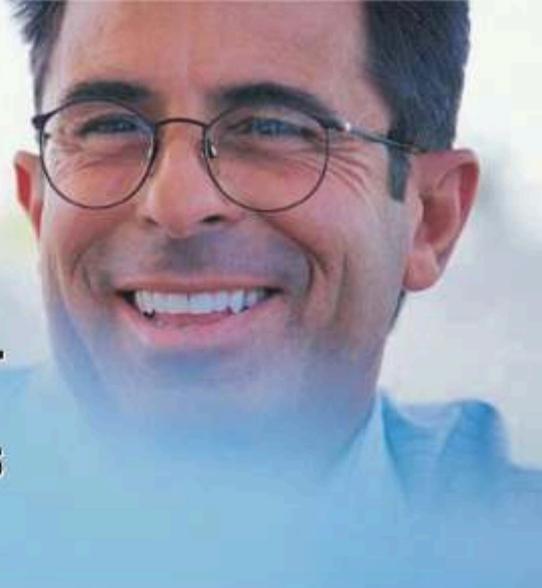
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E-mail: info@interlinkconsultancy.com
Tel.: (022) 2666 6611 / 44



Interlink Marketing Consultancy Pvt. Ltd. 3A, Central Plaza, 166, C.S.T. Road, Kalina, Santacruz (E), Mumbai-400 098, India.
Tel.: (022) 2666 6611 / 44 Email: info@interlinkconsultancy.com Website: <http://www.interlinkconsultancy.com>