

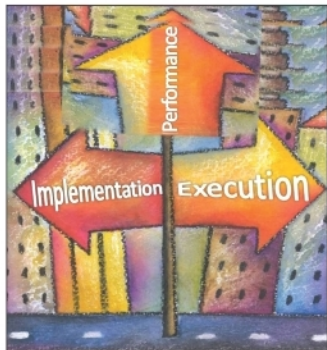
INTERLINK INSIGHT

Perspectives for business performance

NEW METRICS FOR SALES FORCE PRODUCTIVITY

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2 New Metrics for Sales Force Productivity

Dr. R. B. Smarta

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7 Launching Dietary Supplements Successfully in India

Ruth D'Souza

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14 Compulsory Licensing: An Overview

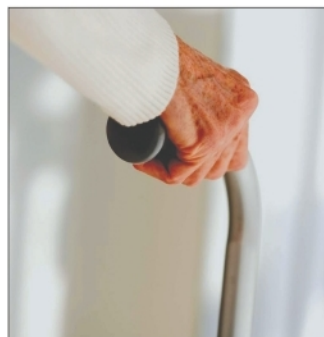
Dr. Rca Godbole

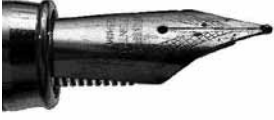
Ever since March 2012, when the Controller General of the Indian Patent Office issued the first ever Compulsory Licence (CL) order allowing the Indian pharmaceutical concern, Natco, to manufacture and sell a generic version of Nexavar (Bayer), this has been a keenly debated topic. A legal expert, through this article shares valuable insights on Scope and nature of Compulsory Licencing, conditions when CL can be evoked, implications of CL and other such pertinent concerns on CL.

18 Increasing Lifespan: Emerging Opportunities for the 'Wellness' industry

Alok Chowhan

It is estimated that the number of elderly in India has increased fourfold during the last 50 years and India is home to over 100 million elderly citizens. With aging comes a host of health challenges such as physical incapacity, deterioration of bodily functions, disabilities and psychological & social issues. Thus, there is an excellent opportunity for a host of 'wellness' products, services and facilities which can range from beauty care products to rejuvenation spas and massage clinics. This article explores the opportunities, threats and challenges of this wellness market for the elderly with interesting facts and figures.





FROM THE PUBLISHER'S DESK

New Frame of Mind

The time has come when the pharmaceutical industry needs to develop new frame work for its success and growth. The old patterns, considerations, markets and even relationships are changing so dynamically that, right from talent acquisition and retention to market penetration & market share increase, all have become equally challenging. Whether you view it from the frame of mind of prescribers, pharmacists, field staff, or from the frame work of industry; everywhere the old frame work is rapidly collapsing to give rise to newer frame works.

In case of pharmaceuticals, the markets have shifted from developed markets to emerging markets. Hence, you need to reorient yourself from developing new metrics for every functional performance, including the Sales force.

The increasing lifespan seen in our country has thrown open the opportunity of Nutraceuticals and wellness. If I from illness is changed to We, the same illness becomes Wellness. I think, it is important to look at both illness and wellness markets together in the coming times.

Patents have also posed a new challenge of compulsory licensing for developing countries like India. This compulsory licensing takes away the competitive advantage of patents. However from the frame work of the country, it becomes essential to look at the process of compulsory licensing for the benefit of overall good.

In this issue of Interlink Insight, you will see the nuances of all the above thoughts. I hope that you as a reader also look at a different frame work which can enable you shape your organization, team and the industry simultaneously. Lets us connect, 'I and We' together so that together we can formulate a different health business for ourselves.

Hope this issue opens up new thoughts and helps you to create a new frame work for future.

Happy reading!

Dr. R. B. Smarta
Managing Director

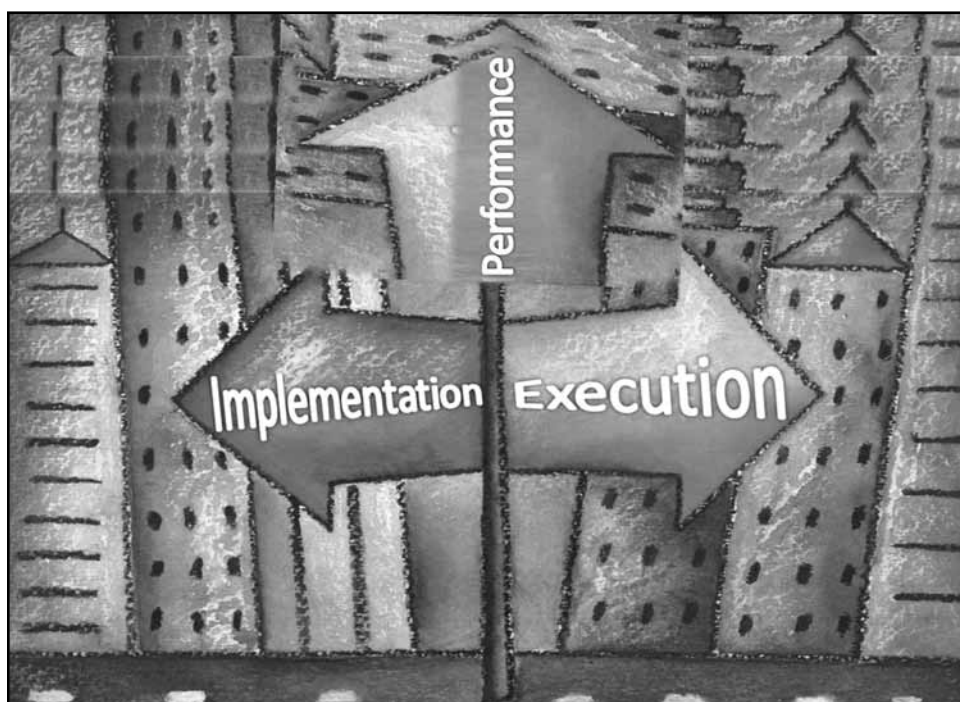
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New Metrics for Sales Force Productivity

– Dr. R.B. Smarta



The sales force productivity measures of Indian pharmaceutical industry, points out the author, are more input oriented than outcome oriented. In most organizations, performance is measured on sheer quantitative elements like expense to sales ratios, quantum of samples, leave-behind literatures, number of calls made per day, etc. But the need today is to critically assess if these productivity measures are still relevant and can there be a newer and more appropriate metrics for Sales Force Productivity. This article presents the changing dynamics of the Indian Pharma industry, questions the wisdom of sticking to the old metrics and outlines the design for a new metrics for Sales Force Productivity.

Gone are the days when Pharma sales force could get ample time to detail their products to the customers. ‘Elevator speech’ is what is required today, to utilize available couple of minutes, or seconds for that matter, to make a call productive. However, it is a ‘Marathon effort’ to arrive at this ‘Elevator speech’ especially in these days, where customers are overloaded with information, which is not only easily accessible but often free, thanks to the internet boom.

Challenges for Pharmaceutical Sales Force

The selling environment has become complex. Patients are more educated. Physicians are least interested in discussing the product features and benefits with Sales Representatives, when it is available at the click of their mouse! This has shrunk the available quality time with prescribers. Prescribers are not going to invest their time in interactions with sales force, unless there is something unique that they have to offer. Lack of effective communication is yet another challenge, especially when there are less of new differentiated products. Generics market has further increased the competition for branded medicines. All these factors have slowed down the pace of prescription volume growth of organisations leading to a stagnant Field Force Productivity.

The Great Mismatch

The current measures of Sales Force Productivity revolve around conventional parameters. Let us take a simple example of an organisation with per capita per month (PCPM) of Rs 5 lakhs in a particular territory. If there are about 200 doctors being met by the sales rep of that organisation, the PCPM will be Rs.2500 per doctor. Taking an average of 25 field days of a Medical Representative, the per capita per day per Dr will be about Rs.100. Assuming 5 products are detailed in a single visit; per capita per day will be merely Rs.20 per product per Dr. This example clearly points out that hardly a

few units of a product are prescribed by the doctor per day!

This brings forth an important question to address, ‘What are the organisations really measuring the Sales Force Productivity on?’ Is it the in-clinic productivity per territory or in-clinic productivity per doctor or for that matter per product? There is lack of alignment between the measures used and activities performed by the sales teams. This gap between conventional performance measures and measures needed in today’s cut-throat competition is huge. Sooner or later, this gap has to be bridged by organisations if they wish to survive and continue growing.

The Call for New Metrics

25 years ago, manufacturing efficiency was an issue when companies were struggling with the long-established parameters for performance measurement. And then the philosophy of total quality management (TQM) took shape. TQM tried to benefit from the contribution of management, employees, suppliers, and even customers, with the purpose of meeting customer expectations. Organisations witnessed huge success just by changing, rather considering the most relevant parameters for performance measurement. Ultimately, what gets measured gets improved!

The sales force productivity measures of Indian pharmaceutical industry are input oriented than outcome oriented. Top management is more concerned about measuring the performance on sheer quantitative elements like samples, leave-behind literatures, number of calls made per day. But the need today is to critically assess whether the productivity measures are still applicable or are merely used to put numbers while filling up the score cards. The time has come for pharma companies to look back if their marketing and sales measures are correct.

Drivers and variables of sales force effectiveness

Pharma players need to understand different drivers and variables involved,

in order to arrive at the factors influencing sales force productivity, some of which are stated below:

1. **Right Customers:** Targeting the best physicians for a product, and prioritizing those physicians with the best prescribing potential
2. **Right Frequency:** Determining the appropriate contact methods and frequency of contact for each physician segment
3. **Right Message:** Developing messages that match the needs and desires of individual physician targets
4. **Right Size:** Hiring and maintaining an optimal number of sales force reps to fulfill the company's needs
5. **Right Deployment:** Creating and managing suitable territories to support the sales model
6. **Right Training:** Providing sales representatives with the support they need in order to shift the focus from the quantity of calls and contacts to the quality of relationships desired, with targets
7. **Right Tools:** Utilizing the correct sales reporting techniques to keep reps focused on their selling responsibilities and not their reporting duties
8. **Right Motivation:** Establishing metrics and compensation to reinforce the desired behaviors among reps

Factors influencing sales force productivity

Sales force productivity is the end product of in-clinic productivity. It is of key significance to define the parameters of in-clinic productivity measures. Given below are some of the vital factors to be addressed and evaluated by top management while formulating a New Metrics:

1. **Engagement plan:** What are the measures for Talent Attraction and Retention? What is the Engagement

plan of the organisation for employees in order to induct, train & retrain them? Is there a sound compensation, product/value incentivisation scheme, performance evaluation and rewards system?

2. **Training and development:** Does management provide enough support to the new & existing medical representatives to continuously strengthen their competencies & competitiveness? At every hierarchical level, are medical representatives getting a chance to develop during interactions or only pressurized for achieving targets?
3. **Stimulation of work:** Are organisations going beyond the conventional 'command and control' option? Is innovation given adequate importance in promotion? Are medical representatives stimulated to come up with new ways of product detailing, objection handling, product reminders and promotion; adhering to scientific approach?
4. **Team player or individual performer:** What parameters exist for assessing whether a medical representative is an individual performer or if he can cope well in case of team targets as well?
5. **Customer loyalty:** Does the organisational design support sales force in establishing long term relations with customers? Do customers get a scientific touch in a fraction of moment?

Bridging the gap

The gap between the measures and the objectives can be bridged by taking practical actions to improve in-clinic productivity

1. **Scientifically focused sales force:** Create a scientifically-focused sales force on the basis of benchmarking and measurement parameters. The scientific foundation is important and

is being done by many pharmaceutical companies, although it incurs considerable cost.

2. **Productivity focused sales force:** Create a productivity-focused sales force that helps prescribers to 'sell the recommended solutions' to patients.
3. **Improving prescriber - patient outcomes:** Offer solutions to prescribers on 'improving patient outcomes' through better communication and get better yield from prescribers.
4. **Connect to customer:** Organisations should strive to connect directly to patient and prescriber groups; through a blend of print media, social media and certain direct interactions.
5. **Monitoring Interactions:** Monitor progress of prescriber-patient interactions initiated by sales force in order to improve relevance of sales efforts from prescriber's point of view.

Critical factors to measure field force productivity

Research on field force productivity highlights 3 key factors to measure the productivity:

1. **Identifying Talent:** Organizations should identify ways to quantify the talents that characterize the top producers and measure the talent. Talent directly relates to productivity.
2. **Engagement plan:** Engagement factors link directly to productivity, profitability, and turnover, as well as other key business indicators. Training sales managers to pay attention to key engagement factors can produce dramatic improvement in a relatively short time frame. A typical ratio of engaged/not engaged/actively disengaged employees in an organisation is 26:55:19, emphasizing the need for a robust Engagement plan.

3. **Improving prescriber - patient outcomes:** In industries that rely on their sales force to generate revenue, people are four times more important in building customer loyalty than the products or services themselves are! Measuring customer engagement is an important device in evaluating the field force whether the market conditions are negative or positive. If the sales force is growing sales, but not adding more loyal customers to the ranks, organisations will be in for a big surprise when the competition introduces an identical product or service. In this era of competition, even satisfied customers are more than willing to switch. Loyal customers stick around.

Designing the New Metrics for Sales Force Productivity Measurement

A 3-step approach could be taken by pharma companies to formulate a new Metrics for Sales Force Productivity Measurement.

1. Step-1: Benchmarking Exercise

Management should focus on getting insights into benchmarking areas like therapy areas, customer groups, number of representatives, communication and promotional strategy so as to come to a consensus on best practices. Management must begin by defining the position they would like to occupy, then study carefully competitors whom they must displace to occupy this slot, study customers whose support they expect to attain this position and many such information.

2. Step-2: Objective Setting

This is a crucial step and management needs to decide on parameters of objectives. The objectives can take a look at talent acquisition, development and retention, engagement of physicians and other relevant customer groups through innovative products, processes, promotion, projects and loyalty from the point of view of

patient groups, therapies, protocols, technology and the organisation.

As a result it is easier to set the

objectives. Mostly old objectives like sales volume, profitability, market share will be derivatives of this new set of objectives.

3. Step-3: Developing the Measurement Metric

Parameters	Measures	Qualification	Review
Talent			
Engagement			
Customer loyalty			

With a metrics developed on critical parameters like Talent, Engagement and Customer loyalty; coupled with a timely review, organisations will surely be able to track the Sales Force Productivity on right measures.

Balance of thinking must shift towards a quantum, rather than piecemeal change!

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Dr. R.B. Smarta, Founder Director of Interlink marketing Consultancy, has more than 40 years of experience in the industry including over 28 years in management and business consulting. Being a thought leader, he has helped 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 industry.

Launching Dietary Supplements Successfully in India

– Ruth D'Souza



The burgeoning nutraceutical industry in India is attracting an increasing number of players with most entrants wanting to get an early entry into the market through launch of dietary supplements. The marketing of nutraceuticals has its own set of pre-requisites & launch strategies, which are different from those of Pharmaceutical marketing. This article attempts to discuss these issues and also throws light on the strategic approaches that will enable successfully launch of dietary supplements in India.

The blurring of boundaries between two industries -food and pharmaceuticals- has led to the emergence of the inter industry segment – Nutraceuticals. This convergence of two industries has created a multibillion dollar industry worldwide. The burgeoning nutraceutical industry in India is also attracting an increasing number of players with most entrants wanting to get an early entry into the market. With the increasing understanding of nutrition and rising number of nutritional deficiency linked diseases, there is growing awareness of the importance of dietary supplements. This coupled with the rising incidence of metabolic disorders in India, doctors and patients have realized that nutritional correction can play a major role in improving the quality of life and preventing or tackling a variety of diseases / disorders.

The Nutraceutical Market Opportunity

Health consciousness, changing trends in population demographics, increasing consumer affluence, increased life expectancy and improved healthcare have all lead to an increasing consciousness of the role of dietary supplements in promoting good health. As a result, the Nutraceuticals’ market has emerged as one

of the fastest growing segments. Analysis of the nutraceutical market in India shows that dietary supplements contribute to almost 64% of the revenues and are primarily driven by the pharmaceutical sector through vitamin and mineral supplements. In 2011, the Nutraceuticals’ market size was valued at USD 1480 Million of which \$950 million was only dietary supplements.

In 2011, Amway India Enterprises achieved market leadership in vitamins and dietary supplements, with a value share of 24%, its flagship brand, Nutrilite being the main source. However, this success came after much struggle to gain acceptance as the Indian consumer mindset needed to be changed. The Indian consumer needed affirmation of his/her decision to use Nutrilite. This affirmation was sought from the doctor who usually ended giving negative endorsement for the brand and encouraged the consumer to rely on balanced diet to fulfill nutritional needs.

Thus while the market is already very attractive growing at CAGR of 13% and expected to reach USD 2731Mn by 2016, it is quite challenging task to launch dietary supplements in India and make them successful.

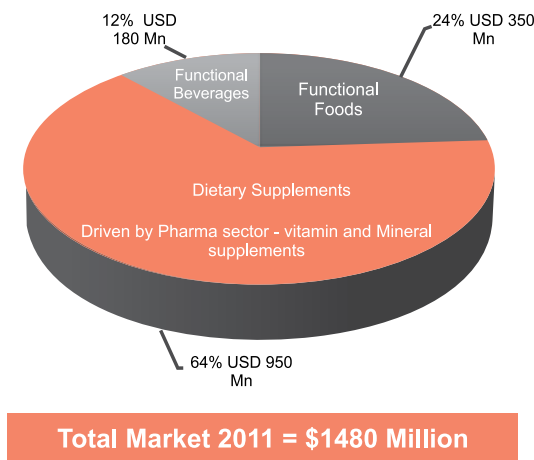
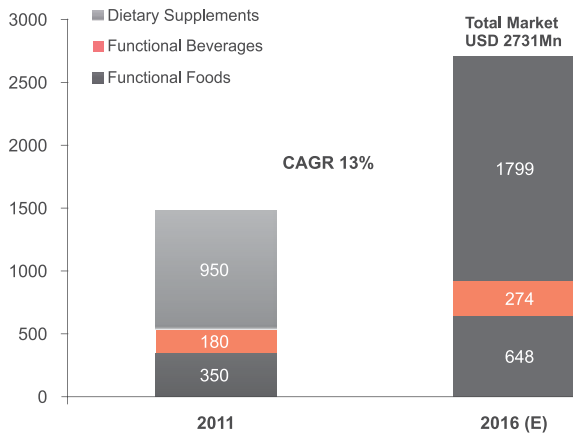


Figure-1: Indian Nutraceutical market – 2011



Source : Frost & Sullivan, Indian Nutraceutical Market Report, 2011

Figure-2: Indian Nutraceutical market - road ahead

The opportunity exists, so does the challenge to meet the requirements of the evolving Indian regulatory framework as well as deliver sales and profit goals in the competitive and complex market place.

In the light of the growing interest in this segment, this article attempts to raise the pre-requisites and strategic approaches for successfully launching dietary supplements in India.

Understanding Dietary Supplements

As per the 'Food Safety and Standards Authority of India (FFSAI)' chapter 22B, dietary supplements are defined as having the following characteristics:-

- Are not a conventional food
- May be formulated in the form of powders, granules, tablets, capsules, liquids, jelly and other dosage forms but not parenterals
- Are meant for oral administration
- Do not include a drug
- Do not claim to cure or mitigate any specific disease, disorder or condition (except for certain health benefit or such promotion claims) as may be permitted by the rules made under this Act
- Do not include a narcotic drug or a psychotropic substance

In the context of the above definition, Dietary supplements can be used in various segments, either to prevent disease or to supplement a nutritional deficiency. Some segments where dietary supplements can be used effectively are outlined below:-

1. **Organ Specific care:** Eyes, bones, joints, brain, heart, lungs, liver, kidney
2. **Disease specific care:** Cancer, diabetes, hypertension, dyslipidemias, asthma, osteoarthritis, osteoporosis, depression, cough, sleep disorders
3. **General care:** Weight management, artificial sweeteners, rejuvenators, immunity enhancers and stress busters
4. **Reproductive health:** Supplementation of deficiencies
5. **Gender and age:** Products on specific nutritional needs, pediatric nutrition.
6. **Sport nutrition:** Meal replacers, protein shakes and protein powders, supplements like creatine and glutamine
7. **Vitamins and minerals:** Various vitamins and specific minerals
8. **Beauty related:** Skin and hair products to repair damage and slow the aging process.
9. **Energy drinks:** Malted beverages, fruit based products and glucose.

Dietary Supplements: Strategic Decisions for successful entry

Strategy is a deliberate choice of purpose. This purpose will define our activities and these activities will define the outcome. A potential entrant into this segment needs to carefully consider the various elements which impact launch and success. Figure-3 depicts key strategic decisions that revolve around the 7 crucial points crucial for successfully launching Dietary Supplements in India. (see figure - 3)

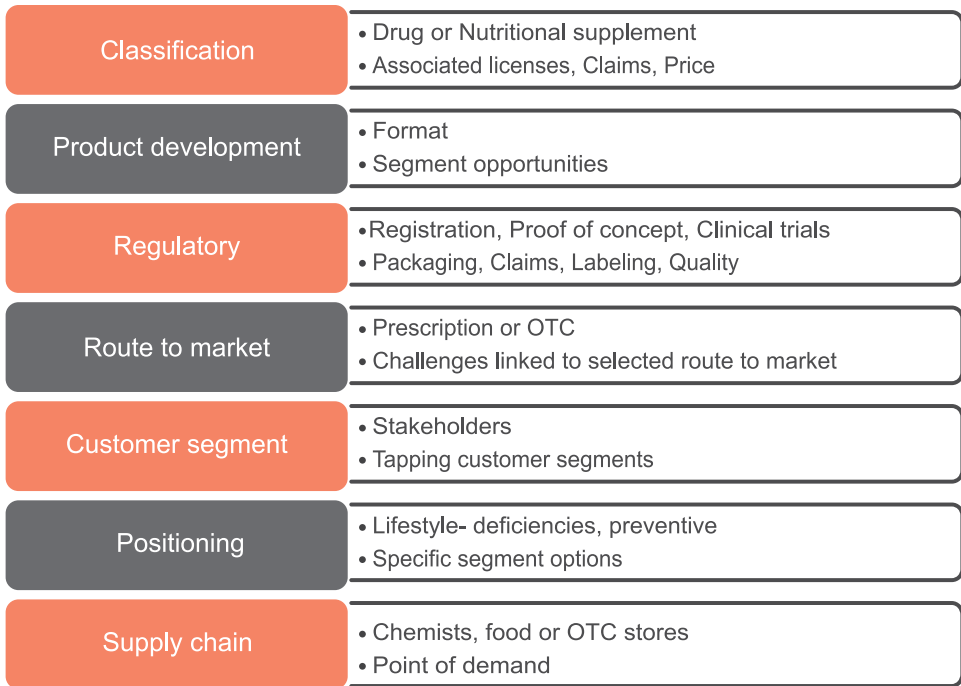


Figure - 3: Successfully Launching Dietary Supplements - key strategic decision areas

1. Classification

Organizations have a choice of launching their dietary supplements either as a drug or as a nutritional supplement and may choose the prescription route or go the non prescription way respectively by obtaining the relevant license. This critical decision is a starting point for success.

For pharma companies who want to extend their portfolios, a drug license is a logical choice since the channel of marketing and distribution is readily available. The company would also be able to make very clear drug claims which may include the ability of a product to mitigate disease or generate some conclusive effect. The down side is the possibility of price control and the fact that a doctor may be more concerned about prescribing drugs for a particular ailment than a dietary supplement.

On the other hand a company which obtains a food license can market the product as an OTC or non prescription

nutraceutical. Still the company may after other considerations choose the route of prescription nutraceuticals. A sustained advertising campaign will be needed to achieve a critical mass and establish a distribution channel. Claims cannot be conclusive and establishing benefits will be a challenge. On the other hand there are benefits of not being subject to price control.

2. Product development

Product development focuses on 2 key factors - product presentation format and available segment opportunities.

- i) **Format:** One can choose from a variety of formats - pill, powder, food additive, biscuit, beverage, energy bar or jujubes. For children jujubes becomes an interesting format. Experiments are also being conducted to present powders in savory flavours to suit the Indian palate, rather than the predominantly sweet flavours that are usually available.
- ii) **Segment opportunities:** The chosen nutraceutical can be targeted for a specific condition like diabetes,

cardiovascular, osteoporosis or the product can be positioned as a general protein supplement.

3. Regulatory

In Contrast to countries like Japan and the USA, where a single regulatory law - Dietary Supplement Health and Education Act (DSHEA) - is applicable, this sector is governed by multiple laws in India, leading to a complex regulatory environment. The registration process is complex and one must consider the following elements to get a clearance to manufacture and market.

- i. Registration
- ii. Claims
- iii. Labeling
- iv. Packaging
- v. Quality

- i) Registration:** This comprises two major areas: registration for product approval and registration for marketing.

Product Registration includes addressing the following

- Selecting right ingredients for the product to be classified as a dietary supplement
- Whether the product is below RDA (Recommended Daily Allowance) nutraceutical
- Whether it is prophylactic or curative
- Whether it is a generic me-too product or a new product or a new indication

Once these aspects are established, the organization will need to demonstrate proof of concept (POC) through CRO's. After the POC, the regulatory FSSAI may recommend abbreviated clinical trials depending on the claims. Regulator authority for a Drug license is FDA while in case of a nutritional license it is FSSAI. Satisfying the regulatory authorities on all these aspects will complete the process for product registration.

Registration for Marketing

The key decision to be taken here is whether one would like to manufacture and market or import the product and market in India. Marketing approval requires complying with the norms for claims, labels, packaging as well as the requirements of the standards of Weight & Measures Act. It is also possible that the regulatory authority may ask for the proof of concept and clinical trials before approving a product for marketing.

ii) Claims

Claims can be of two types -

- a. **Structure & function claims**, which describe the effects of the dietary supplement on the normal functioning of the body. However structure and function claims cannot specify that the food can treat, diagnose, prevent or cure a disease. Claims such as “promotes regularity,” “helps maintain cardiovascular health,” and “supports the immune system” fit into this category.
- b. **Disease-risk reduction claims/ health claims** imply a relationship between dietary components and a disease or health condition. For instance, the health claim for soy protein and its relation to cardiovascular disease reads: “Diets low in saturated fat and cholesterol that include 25 grams of soy protein a day may reduce the risk of heart disease. One serving of (name of food) provides x grams of soy protein.”

iii) Labeling

Labeling is key and depends on what claims have been approved. Labeling norms vary from country to country and have specific requirements like mention of nutrients, calorie information and amount of grams required by body weight. Labeling should also be consistent with positioning and promotion. Unless a claim is specific towards a disease, no specific dosage can be mentioned. Label claims in India are in formative

stage. Just 30 claims are passed by FSSAI and the panel is working on Structure- Functions Claim Platform.

As per FSSAI CHAPTER-IV.23 no person can manufacture, distribute, sell, dispatch or deliver to any agent or broker for the purpose of sale, any packaged food products which are not marked and labeled in specified manner. The labels shall not contain any statement, claim, design or device which is false or misleading in any way concerning the food products contained in the package as well as the quantity or the nutritive value implying medicinal or therapeutic claims.

iv) Packaging

All the above information as per labeling norms is required to be mentioned clearly on the package and on the leaflet so that the consumer can be aware before using. Every food business operator has to ensure that the labeling and presentation of food, including their shape, appearance or packaging, the packaging materials used, the manner in which they are arranged, the setting in which they are displayed, and the information which is made available about them through whatever medium, does not mislead consumers.

v) Quality

In order to provide value and differentiation as well as to promote a sense of comfort in the consumer's mind it is important that a company decides and meets with a specific quality standard. No food business operator can sell or offer for sale any article of food to any vendor unless he gives a guarantee in writing in the form specified by regulations about the nature and quality.

For regulatory purpose, the Food Authority may establish as many Scientific Panels as it considers necessary on:

- food additives, flavourings, processing aids, materials in contact with food

- pesticides and antibiotics residues
- functional foods, nutraceuticals, dietetic products and other similar products
- biological hazards, contaminants in the food chain
- labeling
- method of sampling and analysis.

4. Route to market

What is the best route to reach the target audience is a key decision. Whether one opts for a prescription route or OTC route, each route has its own set of challenges.

Prescription Route – Challenges:

Our research has thrown up some challenges in going the prescription route

- Doctors are uncomfortable prescribing a dietary supplement unless a specific disorder is diagnosed
- Doctors perceive that the cost of therapy increases with additional prescription of supplements
- They are reluctant to prescribe without evidence; yet a company cannot make claims because of lack of concrete medical evidence
- Doctors are concerned with palatability, miscibility (if the product is in a powder format) and thereby patient compliance.
- Currently the prescribing dietary supplement market is geared to child nutrition or pregnancy/ lactation. Focusing on any other indication or segment will mean education and scientific presentation of the benefits to patients.

Nutraceutical players can partner with NGO's and government stakeholders to raise awareness at patient level and conduct "Ask your doctor campaigns" to counter the doctors mindset.

OTC Route – Challenges:

The OTC route also has its own share of challenges. The major challenge

is consumer education, since most of the products are lifestyle related. Palatability of a product becomes key to a patient's decision. Another factor is product performance with the consumer likely to drop out and not indulge in a repeat purchase if there are no visible or perceivable results. Closely linked with this factor are the side effects. Any perceived side effect will not only ensure that the product is dropped by the consumer but will also create negative word of mouth publicity. OTC needs advertising and distribution reach, both these areas mean the ability to have staying power, deep pockets whereas investment levels and risk levels are considerable higher. But then, so are the potential rewards.

5. Customer Segment

This is the key decision on which rests the success of the brand. Potentially a dietary supplement has 3 sets of customers

1. Doctor
2. Nutritionist
3. Consumer

Each of these have their own set of concerns and viewpoints. Since nutrition is not a priority for doctors, they believe that the cost of therapy will go up for a patient. In a situation where he has to make a choice between drug and a supplement he would predominantly choose the former. On the other hand, nutritionists want scientific evidence. This in itself is a contradiction because one cannot make claims which are specific. In case of consumers, there is a need to validate the decision to consume a dietary supplement by consulting a doctor. Quite often the doctor discourages such consumption and emphasizes more on balanced diet.

Ms. Ruth D'Souza, Executive Director of Interlink Marketing Consultancy, is a renowned management consultant and a motivational speaker. With the expertise and experience of over 3 decades in pharma, animal health, diagnostics, nutra & wellness space, she has spearheaded number of strategy consulting and competency development interventions at many NCs and MNCs to improve business performance of client organizations. She is an editor of various publications and a regular writer on management.

6. Positioning

Much has been written and spoken about positioning and there is no need to emphasize how critical it is in the marketing of dietary supplements. However one needs to decide whether the product is going to be positioned as a preventive (like Lutein in age related macular degeneration) or for life style deficiencies (zinc, magnesium, vitamins) or for specific segment options discussed earlier.

7. Supply chain

Depending on the license that one obtains - Food or Drug - the supply chain will vary. If a drug license is obtained, then the chemist becomes the key choice but in case of a food license the options widen. Both the routes also determine the distribution payout in the form of margins.

Conclusion

While the dietary supplement market is highly attractive and is going to expand exponentially fuelled by increasing health consciousness and consumer affluence, in order to gain a critical mass, due consideration needs to be given to all the above aspects so that brands are built to last.

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Compulsory Licensing: An Overview

Dr. R̄cā Godbolé



Ever since March 2012, when the Controller General of the Indian Patent Office issued the first ever Compulsory Licence (CL) order allowing the Indian pharmaceutical concern, Natco, to manufacture and sell a generic version of Nexavar (Bayer), this has been a keenly debated topic. A legal expert, through this article shares valuable insights on Scope and nature of Compulsory Licencing, conditions when CL can be evoked, implications of CL and other such pertinent concerns on CL.

Background

In March 2012, the Controller General of the Indian Patent Office issued an order allowing the Indian pharmaceutical concern Natco to manufacture and sell a generic version of Nexavar. This is the first ever Compulsory Licence (CL) issued in this country. Grant of a compulsory licence was under the provisions of Section 84 of the Indian Patents Act, 1970 for Sorafenib Tosylate (Brand Name: Nexavar). In his order, the patent controller said Natco's application met three key conditions for granting compulsory licences:

1. The German firm was able to supply its drugs to only 2% of the country's patient population and did not meet the 'reasonable public criteria' requirement
2. Its price was not reasonably affordable, and
3. It was imported and not manufactured in the country.

Natco will have to pay a 6% royalty on the net sales to Bayer every quarter. Further, it can only charge Rs. 8,800 for a monthly dose of the drug as committed in its compulsory licensing application regarding this drug.

The following text hopes to put this development into its proper context.

Understanding Compulsory licensing

Compulsory licensing is referred to when a government allows someone else to produce the patented product or process without the consent of the patent owner. It is one of the flexibilities on patent protection included in the WTO's

agreement on intellectual property - the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement. The key purpose of CL is to rectify any type of market failure and to discourage abuse of a patent in any form by the patent holder.

Conditions for issuing Compulsory licensing

Though the TRIPS Agreement does not specifically list the reasons that might be used to justify compulsory licensing, in Article 3, the TRIPS Agreement does list a number of conditions for issuing compulsory licences. However, the Doha Declaration on TRIPS and Public Health confirms that countries are free to determine the grounds for granting compulsory licences.

Normally the person or company applying for a licence has to have tried to negotiate a voluntary licence with the patent holder on reasonable commercial terms. Only if that fails can a compulsory licence be issued, and even when a compulsory licence has been issued, the patent owner has to receive payment; the TRIPS Agreement says "the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization", but it does not define "adequate remuneration" or "economic value".

There's more. Compulsory licensing must meet certain additional requirements: it cannot be given exclusively to licensees (e.g. the patent-holder can continue to produce), and it should be subject to legal review in the country. For "national emergencies", "other circumstances of extreme urgency"

or “public non-commercial use” (or “government use”) or anti-competitive practices, there is no need to try first for a voluntary licence. It’s the only instance when the TRIPS Agreement specifically links emergencies to compulsory licensing: the purpose is to say that the first step of negotiating a voluntary licence can be bypassed in order to save time. But the patent owner still has to be paid.

Implications of Compulsory licensing

Compulsory licensing has implications beyond specific national borders. The fear often expressed is that a liberal CL allowance would de-incentivize research and spread of new drugs in the world. To evaluate this possibility, researchers at the Josef Korbel School of International Studies at the University of Denver identified 24 verified compulsory licensing episodes in 17 nations that occurred between January 1995 and June 2011. Half of these episodes ended with an announcement of a compulsory license, and the majority ended in a price reduction for a specific pharmaceutical product for the potential issuing nation through a compulsory license, a voluntary license, or a negotiated discount. These 24 episodes collectively involved 40 drug patents for 22 unique pharmaceutical products. Interestingly, one of these was in the United States when, in the aftermath of 9/11 over fears of a potential anthrax attack, the American government suggested it would pursue a compulsory license in order to address the potential shortage of the relevant drugs to combat that eventuality. The US government

subsequently secured a significant discount on these drugs.

The overall conclusion reached in this study is that thus far countries have carefully weighed the benefits and risks of compulsory licenses and erred on the side of maintaining protections for issued patents.

Compulsory licensing: Indian scenario

Coming to the Indian patent scenario, the Indian patent regime places significant importance on the “working” of a patent. Indeed, section 84 goes to the extent of stipulating that any patent that has not been worked for 3 years in India after the date of grant of a patent can be subject to a compulsory license (CL) or the Section 83, which explicitly states that a patent cannot be obtained for the mere purpose of importing. It is clear that a patented drug that is not being manufactured in India, but is only being imported into India can be subject to a CL. Section 146 states that information relating to the “working” of a registered patent is to be periodically submitted to the Controller in a form prescribed by the rules.

This specific compliance however, was not observed in the intervening years of the new Patents regime coming into force (2005) till 2010. In early 2010, all the Pharma patent holders in India were required by the Controller General of the Indian Patent Office to submit this information in Form 27. Under an RTI application pertaining to these filings in case of selected drugs (1.Nexavar(Bayer) 2.Dasatinib (BMS), 3.Tarceva (Pfizer & OSI, licensed to Roche), Sutent (Sugen

& Pharmacia Upjohn Inc., licensed to Pfizer), Pegasus (Roche), Viraferonpeg (Schering), Entecavir (BMS), it was made public that none of the pharmaceutical firms that the RTI seekers studied had provided full and complete Form 27 information. In some cases, Form 27 has not been filed at all, and in others, the information provided was woefully inadequate.

In light of the Natco case, the patent office acted on the grounds that the life-saving drug was not available at a reasonably affordable price even three years after the Nexavar patent had been granted to Bayer. The important point here is that “excessive vs reasonable pricing” may be complex and time consuming to determine for the courts. It is thus relevant to mention that all the drugs, for which Form 27 information has been provided, make more than Rs ten crores a year (USD 2.2 million). In case of Nexavar the information submitted by Bayer reads as follows:

Patent No. 215758 Bayer Corporation

PRODUCT NAME: Nexavar

PATENT EXPIRY: 2021.

08-09 Not Worked

09-10 Worked 4,665 packs were imported but only 1,679 packs sold Rs. 16.5 crores in sales.

Till the patent expiry in 8-10 years, the product is expected to make **Rs. 165 – Rs. 180 crores = US \$ 40-45 million.**

Compulsory licensing in China

China’s recent announcement allowing officials to issue compulsory licenses (CL) to local firms in cases of state emergencies, unusual circumstances or in the interests of the public comes on the heels of a compulsory license issued by the Indian government for Bayer. In addition, Beijing is moving to change the prices the government pays on about 100 drugs that had differential (or what the industry calls “preferential”) pricing, which were all manufactured by Western and European multinationals. The drugs covered under this preferential pricing scheme were protected by the

Chinese government almost 20 years ago in an attempt to address concerns pharmaceutical companies had about intellectual property (IP) theft. In many cases, the patents on these drugs have run out, but the Chinese government has stood by its commitment to protect these products from domestic competition. China did not make these changes to its IP regimen carelessly. This was a deliberate adjustment that more than likely had a specific portfolio of drugs in mind. In the short term, Beijing is likely to find it has gained the upper hand in negotiations with its pharmaceutical suppliers because of this move just as US did.

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Increasing Lifespan: Emerging Opportunities for the ‘Wellness’ industry

– Alok Chowhan



It is estimated that the number of elderly in India has increased fourfold during the last 50 years and India is home to over 100 million elderly citizens. With aging comes a host of health challenges such as physical incapacity, deterioration of bodily functions, disabilities and psychological & social issues. Thus, there is an excellent opportunity for a host of ‘wellness’ products, services and facilities which can range from beauty care products to rejuvenation spas and massage clinics. This article explores the opportunities, threats and challenges of this wellness market for the elderly with interesting facts and figures.

‘Introduction: A Preview of Elderly population’

A major emerging demographic issue of the 21st century is the ageing of population as an inevitable consequence of the demographic transition experienced by most countries. Across the world, declining fertility and increased longevity have jointly resulted in higher numbers and proportions of older persons 60 years and above.

At the global level, the number of those over age 60 is projected by the UN Population Division to increase from just under 800 million in 2011 (representing

11% of world population) to just over 2 billion in 2050 (representing 22% of world population). The “oldest old” – i.e., those aged 80 and over – is projected to increase by a factor of 26.

Indian scenario

India’s elderly population has almost reached 100 million mark during 2011. As per analysis of census data and projections, elderly population in India is expected to reach 173.18 millions in year 2026, accounting for nearly 43.14% increase. Elderly population constitute nearly 10% of the total Indian population of 1.21 billion (2011 data)

(see Figure-1)

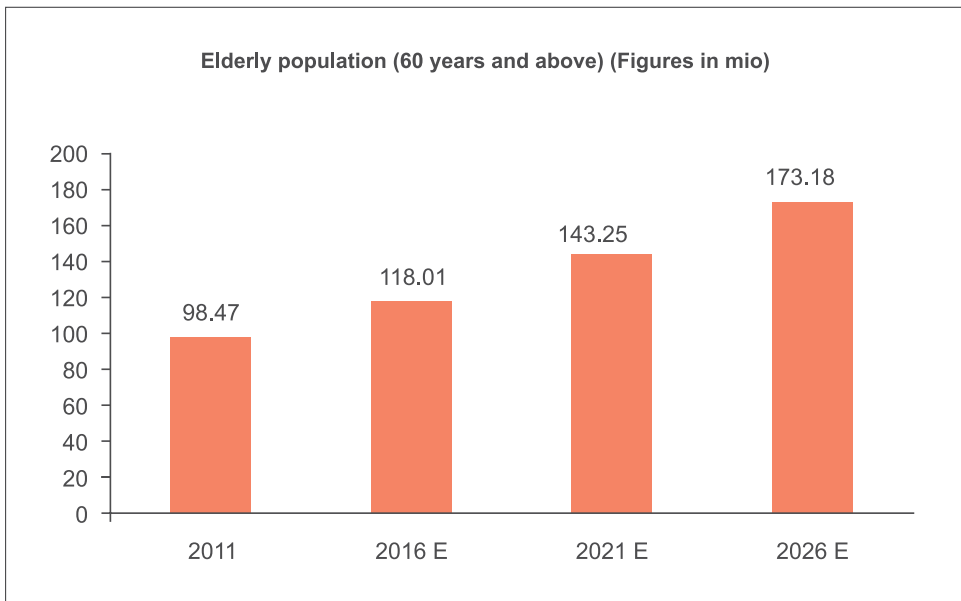


Figure 1: Elderly population - Indian Scenario (Elderly population constitutes nearly 10% of the total Indian population of 1.21 billion: 2011 data)

Health related issues faced by elderly:

The prevalence of heart diseases among elderly men and women was much higher in both urban as well as rural parts of India constituting to almost

47% followed by urinary problems. Most common disability among the aged persons was loco motor disability as 3% of them suffer from it, followed by hearing disability (in 1.5%). (see Figure-2 and 3)

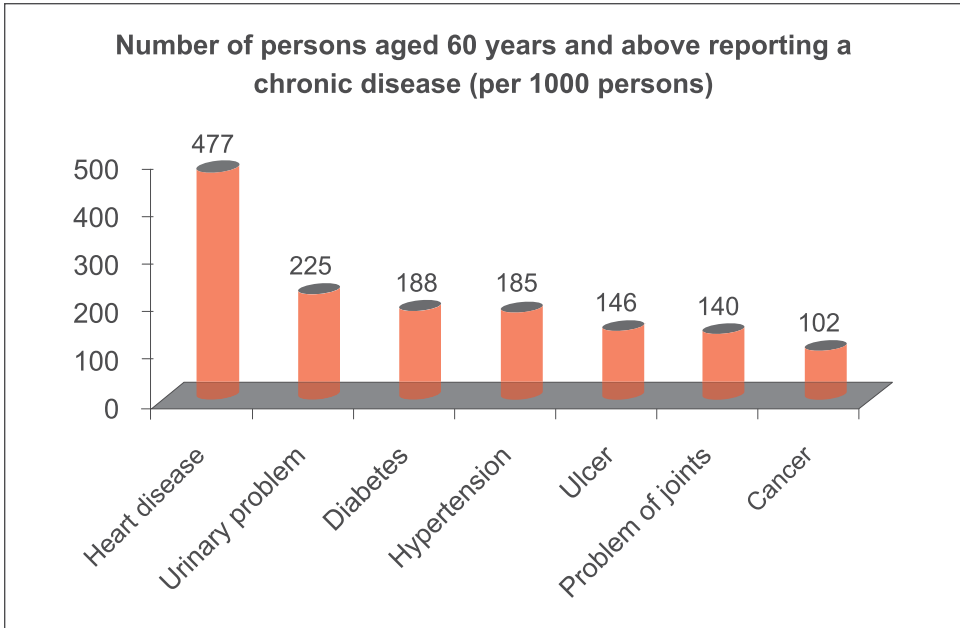


Figure-2: Health related issues of elderly population - chronic diseases

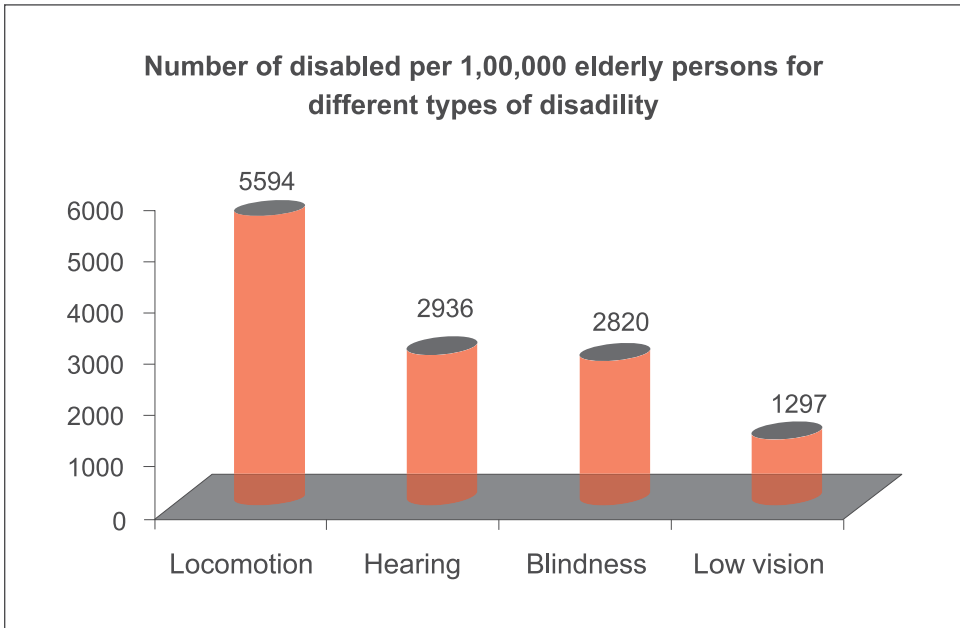


Figure-3: Health related issues of elderly population - types of disadility (The prevalence of heart diseases among elderly men and women was much higher in both urban as well as rural parts of India constituting to almost 47% followed by urinary problems. Most common disability among the aged persons was loco motor disability as 3% of them suffer from it, followed by hearing disability, in 1.5%)

Social issues faced by elderly:

Apart from the major non – communicable diseases like heart disease, urinary problems, hypertension and other disabilities, elderly population

in India also face a number of social issues which affects their psychological well being to a greater extent.

Nearly 60.1% of elderly population in India, fall prey to verbal abuse mainly

from their family members, followed by physical abuse constituting to 47.7% and disrespectful conduct and treatment by family members (36.1%). This results in frustration, helplessness, and at times aggression in the elderly which in turn causes psychological as well as physiological imbalance which may aggravate their physical conditions.

Wellness – A growing demand for elderly

The NABH (National Accreditation

Board for Hospitals & Healthcare Providers) defines Wellness as “a state of a healthy balance of the mind and body that results in overall well-being”. Today the overall wellness market in India is estimated at INR 490 bn to 500 bn. By 2014 it is estimated that the Indian wellness industry will grow at a CAGR of 20% to reach INR 875 billion. The wellness market encompasses the following. (see Table-1)

Core Segments	Sub Segments (%Contribution)	Value in (INR)	Key Players
Beauty care (INR 200 Bn)	Cosmetic products – 60 %	120 Bn	HUL, P&G, Dabur, L'Oreal
	Salons – 35%	70 Bn	VLCC, Lakme, Shahnaz Hussain, Jawed Habib
	Cosmetic treatments – 5%	10 Bn	Kaya skin clinic, VLCC
Fitness and Slimming (INR 40 Bn)	Slimming products – 12%	4.8 Bn	Himalaya, Dabur, Herbalife
	Slimming services – 17%	6.8 Bn	VLCC, Vibes
	Fitness equipments – 20%	8 Bn	Cardio fitness, Proline fitness, Cardiomed
	Fitness services – 50%	20 Bn	Talwalkar's, Gold's Gym, Fitness one, Snap fitness
Nutrition (INR 130 Bn)	Dietary supplements – 25%	32.5 bn	Amway India, Dabur
	Health and wellness Food & Beverage – 75%	97.5 bn	Pepsico, Britannia
Rejuvenation (INR 4 Bn)	Spas & massage services	4 Bn	Four Fountains, Chandan Sparsh, Ananda Spa, Amatra etc
Alternative therapies (INR 120 Bn)	Herbal products	120 Bn	Kottakal Arya Vaidyashala, Arya Vaidya Pharmacy, Dr Batra's, Dabur, Himalaya and others

Table 1: (Source: 3rd Annual Wellness Conference - FICCI -September 2011, www.euromonitor.com/vitamins-and-dietary-supplements-in-india/report.)

Considering, the fact that the elderly in India face many health as well as psychological issues, there is clearly a need for ‘Wellness solutions’, which can be considered to be as an area of opportunity for many pharmaceutical and healthcare players to venture into. Elucidated below are few examples of healthcare players encashing population opportunities of increasing their foothold into wellness space by catering to needs of elderly population.

- 1) Nestlé’s Resource SeniorActiv’: To tackle the nutritional needs of elderly, Nestle launched geriatric supplement line named “Resource SeniorActiv”. It is a unique oral nutritional supplement specifically designed for older adults to help them regain strength and remain independent.

Product Benefits

- Improve nutritional status
 - Regain strength and energy after an illness or surgery
 - Maintain functional abilities, by supporting physical strength and cognitive health
- 2) Lupin’s Wellness Noni: Lupin a major pharmaceutical company in India entered the wellness category by launching its wellness product named “Lupin NONI” which is useful for elderly care by reducing blood cholesterol level, depression, insomnia and other psychological problems.
 - 3) Sandu Pharma’s Spa & Wellness centre: Sandu Pharmaceuticals Ltd. ventured into rejuvenation segment of wellness industry, by launching “Sandu Ayurvedic Spa and Wellness Center”.
 - 4) Zydus’s Wellness division: The company promotes healthy living and is present in niche segments with strong brands like Nutralite, Sugar-

Free, Acti-Life among others. While Sugar-Free has a 90% market share, the other brands are tapping new grounds with the division registering 60% growth in profits.

- 5) With geriatric care slowly gaining importance in the city and exclusive clinics being established for the purpose, healthcare company Senior Care India launched its elderly assisted living services in Chennai. They offer quality medical and non-medical personal care services to elderly people in the comfort of their homes.

Wellness Market for the Elderly: Opportunities, Threats and Challenges

Opportunities:

- Growing elderly population, constituting nearly 10% of total Indian population of 1.21 billion
- Wellness market is estimated to grow at a CAGR of 20% from year 2011 to 2014.
- Rise in psychological as well as physical issues related to elderly in India
- High disposable income among elderly due to increase in pension income by the central and state governments as well as increased income-tax exemption limit
- Elderly understand the value of money, thus offering good deals make them brand loyal
- Desire to look younger by staying fit and healthy
- Elderly have more time to spare as they have fewer domestic pressures.

Threats:

- Many unorganized players in the wellness space, hence maintaining consistency of services and offerings is a threat

- Entry of foreign players into wellness space by private equity route can be a threat to Indian players
- Input costs of rent, manpower and consumables constitute about 50 to 60% of revenues for wellness service providers which can be a threat to achieve profitable margin
- Lack of qualified manpower in areas like fitness, beauty and rejuvenation services etc.
- Acceptance and penetration of QCI-NABH guidelines in wellness space is low and hence low awareness of quality guidelines among industry participants. (QCI – Quality control of India, NABH – National Accreditation Board for Hospitals & Healthcare Providers)

Challenges:

- To overcome talent crunch, industry will require over 600,000 additional skilled, certified and licensed personnel during the next five years.
- Minimum quality norms need to be defined across wellness segments to ensure adherence to control malpractices within the industry
- Implementation and acceptance of quality accreditation across various industry categories within wellness to suitably modify QCI-NABH guidelines in line with the needs and specifications for each category.
- Ensuring consistent experience across touch points, since - many

large players and international brands have used the franchise route for scale-up

- Able to regionalize the offerings from wellness players across India, on account of significantly varying consumer preferences.

Conclusion

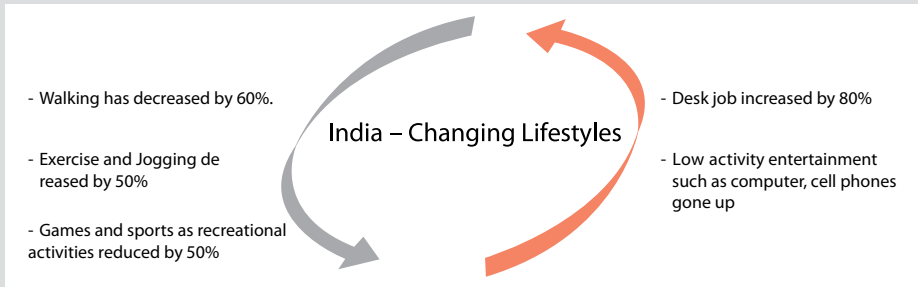
Aging is inevitable and in the current Indian scenario the burgeoning aging Indian population is ready to break convention and indulge in taking care of their health and well being using a plethora of options available to them. It is said that, ‘When grace is joined with wrinkles, it is adorable and then there is an unspeakable dawn in happy old age.’ This philosophy presents a huge potential for the ‘Wellness’ industry, which is yet to be tapped by the Healthcare industry.

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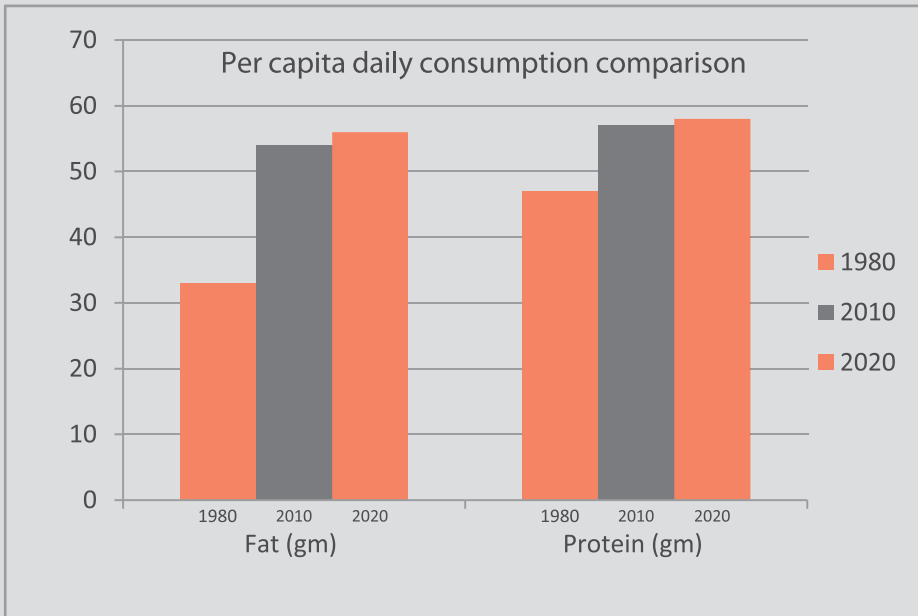
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Mr. Alok Chowhan is associated with Interlink as a research associate. He has handled various market research projects in the space of pharmaceutical, animal health, nutraceutical and wellness space. He has worked on new product launches like INTER_xact™ - video based training package for Indian pharmaceutical industry.

Nutraceutical Industry Opportunity Snapshot



• India – Changing Food habits



India – Alarming Facts

- Lifestyle diseases account for 53 per cent of all deaths and 44 per cent of disability-adjusted life-years in India, according to the World Health Organisation’s Global Burden of Disease Study.
- Every fourth diabetic in the world is an Indian
- 60 per cent of the world’s cardiac burden is borne by India
- Over 800,000 new cases of cancer occur every year.
- Over 30 per cent of adults are seriously overweight.
- Nutrition related problems to be a major concern in India

Opportunities to be Tapped

With the increasing health consciousness among the Indian population, increasing awareness of the concept of wellness and preventive healthcare, with the huge ageing Indian population, with the rise in disposable income and growing affluence, it is certain that the demand for Nutraceuticals in the country will be high. Companies that can deliver what the people want and can delight the Indian customers by their innovative products and marketing strategies are going to be the market leaders.

(Interlink Knowledge Cell)

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