InterlinkInsight

Perspective For Business Performance



CHANGE IS INEVITABLE

FROM THE PUBLISHER'S DESK



'An Essence of Stability & Growth'

If we can set innovation and leadership on the same path, there is a hope for an innovation-driven leadership in our Industry, where stability and growth co-exist!

Can growth and stability co-exist?

'An Essence of Stability & Growth in pharma is hidden in creating brand system around field staff. Lead article shows that growth and stability can co-exist. Both growth and stability are needed to revitalize business and mature brands along with managing customers.

Many questions crop up like:

- 1. Is it time to focus on patients to derive growth?
- 2. Do "Connecting Dots" Make In India a part of global initiative?
- 3. Is 'The Heart of Pharmaceutical Marketing' is medico-marketing?
- 4. Can we go beyond India say Africa, which is a vast and highly diverse continent with great potential for growth?

May be in this issue of Interlink Insight you may get few ideas which are shaped or can be shaped to bear fruits.

Similarly, as we actualize in day to day life the **presence of nutrition** in our health programs, 'Controversial Outlook of Anti-Oxidants' would provide you a **fresh outlook**.

Stability and growth are important factors and innovation always looks forward to integrate both to provide size, shape and momentum!

Hope this Interlink Insight issue makes a worthy reading.

On your feedback we thrive.

Wish you the best of reading!

Yours Sincerely,

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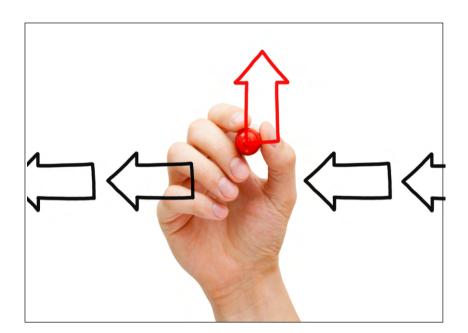
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Exploring Better Model for Change



The pharmaceutical industry is in a constant state of flux and to stay ahead one needs to adapt to the cycle of changes. Read the article to get deeper understanding on how the pharmaceutical industry needs to stay abreast of the changes in order to be effectively engaged as discussed in an inclusive way by Dr. R. B. Smarta.



EXPLORING BETTER MODEL FOR CHANGE

Pharmaceutical industry is a global industry dealing with the varied and dynamic medical conditions of populations worldwide. This puts the industry at the heart of the healthcare system, compelling the industry professionals to look at it in a different way.

Change is one constant thing in every industry and the pharmaceutical industry is no exception. It's a constant state of flux and to sustain and stay at the top you need to adapt to the cycle of changes. This cycle of changes provides growth opportunities to the organizations, helping them ride the wave.

In near future the world is likely to face Volatility, Uncertainty, Ambiguity and Complexity (UVAC) along with Black Swans (Unpredictability). UVAC's world expresses the systemic failures and behavioral failures, imperative to organizational failure. The UVAC's world is driven by digitization, sustenance and rise of developing world. This situation can be translated to various industries such as pharmaceuticals, automation, nutrition etc.

Whatever maybe the development, any forward thinking industry needs to stay abreast of the cycle of changes in order to be effectively engaged.

Global Pharmaceutical Dynamics

The global pharmaceutical market is worth USD300 billion per annum, which is expected to grow to USD400 billion within the next 3 years. One-third of this market is controlled by the 10 largest drug companies, many with sales more than USD10 billion per year and profit margins of about 30%.

Companies currently spend one-third of all sales revenue on marketing their products, roughly twice what they spend on R&D. The key decision makers in these drug companies share the common goals of improving health outcomes while controlling costs and expanding access.

The industry is faced with unparalleled dynamics like high patent expirations, rise in demand for medicines, accessibility to fewer new medicines and modest uptake of available medicines. As a result, these dynamics are driving rapid shifts in spending between branded drugs and generics and between spending in developed countries and pharmerging countries. Innovative products are expected to be launched, bringing new treatment options to patients with lifestyle diseases and debilitating diseases as well as driving the markets for the next few years.

In pharmerging markets, improved access and strengthening economies would drive higher demand, particularly for generics.

Specialty medicines are expected to witness continued growth leading to increased uptake. Oncology, asthma and COPD, lipid regulators and angiotensin inhibitors are going to be the key therapy areas for the years to come.



8 Forces Acting on the Pharmaceutical Industry

I. Generic Revolution

The pharmaceutical industry is at the crossroads today, of generic revolution, with the patents going off the cliff. With rising drug prices, cost-effective generic drugs have a crucial role to play. As a result, many Governments are actively involved in promoting this generic revolution. This move will contribute for sustaining health care systems worldwide.

2. Changing Trends of Diseases

There have been shifts from infectious diseases to chronic diseases for past 200-300 years at different rates and dynamics across the globe, termed as the epidemiological transition. Globalization, urbanization, increased lifespan, exploding population, dietary changes, public health advances, environmental and climatic changes are the factors of this transition.

Diseases like cancer, heart disease and diabetes are becoming the leading cause of death and disability globally. The change is driven by a adaptation to unhealthy lifestyles, with smoking and alcohol use springing child malnutrition over the last 20 years to become the second and third leading risk factors for disease.

3. Patient Centricity

In today's world, patients are consumers first, with both the freedom and responsibility that comes with making more decisions and spending money on their treatments. Consumers have become more engaged in their own healthcare decision-making. The patients are playing a much more proactive role in their care, with technology serving as the key enabler to empower consumers and providers with the right information, at the right time. Patients are no longer recipients of healthcare, they are active participants. These trends represent a significant

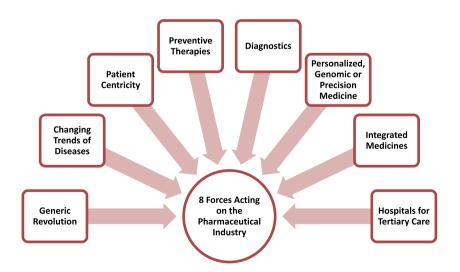


Fig. a 8 Forces Acting on the Pharmaceutical Industry
Source: Interlink Knowledge Cell

opportunity for the most patient-centric and forward-thinking organizations

4. Preventive Therapies

Acharya Charaka seems to have been an early proponent of 'Prevention is better than cure' doctrine. Increasing demographic and psychographic segmentation within the population has led to a desire to stay healthy and live a long life. A growing number of governments in both developed and developing countries are also trying to shift the focus from the treatment of disease to its prevention. Social and economic pressures are gradually causing a sea-change in attitudes towards healthcare.

The younger generation today has come to understand the criticality and constraints of modern medicines. The younger generation does not like to fall sick and would like to work on themselves to stay healthy by balancing nutrition, thus, bringing the pharmaceutical industry at a higher level of competition, limitation, collaboration and consolidation at solution level.

5. Diagnostics

In pharmaceuticals, the overall performance is determined by diagnosis, since the best treatment can be chosen only after a proper diagnosis of the condition. Genetic disposition and damages along with health consciousness has given rise to genomics and genome based diagnostics. The arrival of genomics as a science of clinical significance was underscored by AstraZeneca's announcement on April 21st that it would form a collaboration to sequence 500,000 samples taken during clinical trials it has conducted over the years. According to the British-Swedish firm, it plans to see 2m genomes or so studied over the next decade. It all bodes well for the future of genome-based diagnosis. A report published in 2013 found that nearly a third of drugs in clinical development are associated either with a known DNA variant or with a variation in the structure of a specific protein, ultimately traceable to DNA. The presence in, or absence from, a patient of such variant allows drug makers to know whether their products are likely to work in that individual. This supports more precise genetic tests and molecular diagnostics for more targeted treatments.

6. Personalized, Genomic or Precision Medicine

Many researchers and healthcare professionals globally are calling for a more personalized approach aimed at preventing a medical condition and tailoring treatment once it's there. This can be called personalized medicine, genomic medicine or precision medicine. The National Human Genome Research Institute maintains that personalized approach to medicine includes individual's genetic profile to guide decisions made in regard to the prevention, diagnosis, and treatment of disease. While it's important to remember that genes are not destiny, they do provide information that can lead us to make more informed decisions about our health and healthcare. If you get sick, knowing your genome or the molecular basis of your disease can be an important piece of evidence for doctors seeking the most favorable treatment plan for you. In the case of cancer, genetic



tests could lead to successful drug treatment rather than radical surgery.

7. Integrated Medicines

Integrated medicine is comparatively new approach to healthcare and medicine and is whole body healing oriented. It uses various biological therapies like nutraceuticals, alternative medicines as well as pharmacological agents for prevention, treatment or for maintaining optimum health.

With increasing consciousness about health, fitness and overall well-being people have shifted towards wellness and prevention of diseases rather than treating them. In this new age, preventive healthcare system is given more preference than curative healthcare system.

Some other factors fuelling this shift are escalating healthcare costs, increasing awareness and education, rise in penetration of new medicinal treatment approaches etc.

8. Hospitals for Tertiary Care

The healthcare space has witnessed a rise in hospitals for tertiary care for the past few years. This tertiary care is a focused consultative health care, usually for inpatients and referral patients from a primary or secondary healthcare professional. This tertiary care has healthcare personnel and facilities for advanced medical investigation along with treatment. Tertiary care services include cancer management, neurosurgery, cardiac surgery, advanced neonatal services, palliative, and other complex medical and surgical interventions.

Defining Moment

The defining moment for the pharmaceutical industry requires certain strategic elements in place.

The industry needs to provide health solutions in terms of integrated medicines with respect to modern medicines, traditional medicines, alternative therapies, and nutraceuticals.

There needs to be a shift of focus from cure to care of the patient, thus establishing the requirement of a total care model.

The intent of the industry should be to provide affordable and accessible medicines to the consumers without compromising on the quality of the products and keeping patient safety at the front.

Due to quality issues, dwindling safety profiles of drugs and ethical issues, the image of the industry is not very high. Thus, it is crucial to have methodologies in place to increase this image of the industry for consumers' satisfaction.

The industry needs to take up projects that will cater to rural and poor populations to erase inequalities existing in the healthcare system and also concentrate on 'care

and cure' formula with patient centricity.

It is also important for the pharmaceutical industry to adopt a multi-prong approach to address diversity, lifestyle as well as behavioral issues like doing justice to the emotions of patients along with demographic dividend of emerging markets, and biotechnological innovations.

At the same time, it is crucial for the national and multi-national organizations to define what they really require in order for the eight forces to act simultaneously.

About the Author

Dr. R. B. Smarta, Founder & Manager Director of Interlink Marketing Consultancy Pvt. Ltd., has more than 45 years of experience in the industry including over 30 years in management and business consulting. Being a though leader, he has helped the management of a number of organizations set up and grow through strategy consulting, sales & marketing effectiveness, organizational development interventions, successful mergers & acquisitions and innovative video-based training packages for the Indian pharmaceutical, nutraceutical, diagnostics, critical care and healthcare domains.







The Power of Nutraceuticals



Nutraceuticals, a hybrid of 'nutrition' and 'pharmaceuticals' is taking the world by storm. It is changing the landscape of health and wellness globally. Read on to get deeper and detailed insights on the global and Indian perspective of nutraceuticals as disscussed in an inclusive way by Dr. Dilip Ghosh.



THE POWER OF NUTRACEUTICALS

Nutraceutical is a hybrid word of 'nutrition' and 'pharmaceutical'. According to the Merriam Webster Dictionary, the term 'nutraceutical' is defined as 'a foodstuff (as a fortified food or dietary supplement) that provides health benefits in addition to its basic nutritional value.' Nutraceuticals, in general, are food or part of food playing a significant role in modifying and maintaining normal physiological function that maintains healthy human beings.

The term 'nutraceutical' was coined from 'nutrition' and 'pharmaceutical' by Stephen De Felice, founder and chairman of the Foundation for Innovation in Medicine (FIM), Cranford, NJ in 1989. According to De Felice, nutraceutical can be defined as, 'a food (or a part of food) that provides medical or health benefits, including the prevention and or treatment of a disease.' On the other hand, Health Canada defines nutraceutical as 'a product prepared from foods, but sold in the form of pills, or powder (potions) or in other medicinal forms, not usually associated with foods.' Nutraceuticals are found in growing number of products emerging from (a) the food industry, (b) the herbal and dietary supplement market, (c) pharmaceutical industry, and (d) the newly merged pharmaceutical/agribusiness/ nutrition conglomerates.

Categorisation

Nutraceuticals can be categorised in different ways based on food sources, mechanism of action, chemical nature etc. The food sources used as nutraceuticals are all natural and can be categorized as:

- I. Dietary Fibre
- 2. Probiotics
- 3. Prebiotics
- 4. Polyunsaturated fatty acids
- 5. Antioxidant vitamins
- 6. Polyphenols
- 7. Herbals
- 8. Spices

Market

The Broad nutraceutical market constitutes the functional foods, herbals/botanicals and dietary supplements market. Nutraceuticals offers opportunities for pharmaceutical companies to make their products more consumer-oriented, and for food companies to create brands with a medical halo. Positive consumers view of nutritional products for managing health has been driving the global nutraceutical industry. The global nutraceutical market was valued at around USD250 billion in 2014 and is expected to reach around USD385 billion by 2020, at a CAGR of 7.5% from 2016 to 2021 (BCC Research, 2014).

The current consumer trend is more preventive rather than addressing pressing health issues, which involve huge healthcare costs in developed countries. There is a significant shift in the consumer preference from synthetic ingredients to natural and organic ingredients and foods which are obtained from non-GMO (Genetically Modified Organism) extracts. Consumers prefer the nutraceutical foods to



pharmaceutical drugs (Ghosh & Smarta, Pharmaceutical to Nutraceuticals: A Shift in Disease Prevention, 2016).

The leading nations in the global nutraceutical markets are United States, Japan, Israel and Germany. Rising consumption of dietary supplements among the baby boomer generation and booming food and beverages market is driving the US nutraceutical market which is expected to reach USD90 billion by 2020 at a 6% CAGR. This is followed by Asia-Pacific. 47% of the Japanese population consumes nutraceutical products which can be contributed to the growing ageing population. Germany, Netherlands and Sweden have emerged as the key nutraceutical innovation hubs in Europe, while United Kingdom and Spain have emerged as the key test markets for new products.

Indian nutraceutical market is filled with promise. Due to rising awareness about health, fitness and changing lifestyle, India's nutraceuticals market is likely to touch USD6. I billion by 2020 from the current level of USD2.8 billion, growing at a CAGR of 17% (joint study by Assocham and RNCOS, 2015). According to this study, India accounts for around 1.5% of the global market, which is anticipated to increase owing to the country's large population base, increasing urban belt and awareness.

Nutraceuticals for Ageing Population

In the last few decades nutraceuticals have entered the health market as a reliable and attractive means of preventing diseases.

Today's society is increasingly health-concerned and nutraceuticals may be especially relevant for preventing or delaying a number of age-related diseases, i.e. arthritis, cancer, metabolic and cardiovascular diseases, osteoporosis, cataracts, brain disorders, etc. Aging is a major point of concern for public health, since older ages are associated with an increase of the above mentioned chronic-degenerative disorders.

Older generation needs increasing support of medical and social attention and have significant effects on social, economic and clinical burdens. Oxidative stress, systemic low-grade chronic inflammation and the impairment of hormonal, fibrinolytic and immunological status are major risk factors underlying aging along with age-related diseases such as osteoarthritis, cancer, type 2 diabetes, Alzheimers, cognitive decline, obesity, osteoporosis, metabolic syndrome, cardiovascular (CVD) and cerebrovascular diseases, amongst others.

Human life expectancy is continuously growing and by 2025, 15-20% of the world population will be represented by persons aged 65 years and older. To date, only a few nutraceuticals can be considered useful for prevention and/or treatment of age-related diseases. Further, long-term placebo-controlled trials in large cohorts of elderly subjects are needed to evaluate the effectiveness of nutraceuticals.

Regulatory Hurdles

Regulations around nutraceuticals vary from one country to another and are changing all the time. Marketers/ manufacturers will have to work closely with regulatory authorities to anticipate market opportunities that arise when the rules

are altered. In the United States, the term nutraceutical has no legal definition and is commonly used in marketing purposes. The Food and Drug Administration (FDA), under the Dietary Supplement Health and Education Act of 1994 (DSHEA), is ensuring that the dietary supplement or ingredient is safe before it is marketed.

The European Food Safety Authority (EFSA) does not use the term nutraceutical but 'food supplement' in relation to concentrated sources of nutrients or other substances with a nutritional or physiological effect whose purpose is to supplement the normal diet. They are marketed 'in dose' form i.e. as pills, tablets, capsules, liquids in measured doses, etc.

Indian regulator, the Food Safety and Standards Authority of India (FSSAI) has published a draft notification as 'Food or Health Supplements, Nutraceuticals, Foods for Special Dietary Uses, Foods for Special Medical Purpose, Functional Foods, and Novel Food Regulations, 2015' which covers nutraceuticals.

Recent Controversies

In recent years, increased surveillance of the category in light of New York Attorney General (NY AG) Eric Schneiderman's 2015 investigation of herbal supplements sold at GNC, Target, Walgreens and Walmart, has ignited a national debate over the quality and safety of such products. It's well agreed that consumer confidence has certainly been shaken by recent events. Industry leaders still believe that consumer confidence is not completely lost and it can be regained; but the industry needs to prove they have evolved into a quality-focused one.

Despite consumer concerns, the dietary supplement industry has still managed to maintain growth over the past year. According to SPINS data for the 52 weeks ending May 15, 2016, sales of herbal and homeopathic supplements grew 16.4%, earning nearly USD1.7 billion.

Challenges

Currently, the rapidly growing nutraceutical industry is facing many challenges such as:

- I.Lack of authenticity of active principle due to unavailability of reference materials or marker compounds.
- $2. Lack \ of \ understanding \ of \ molecular \ interactions \ between \ bioactive phytochemicals within the same plant.$
- 3. Variability in origin of raw materials (e.g. Chinese vs. American ginseng).
- 4. Variability of processing raw materials.
- 5. Lack of standardisation of extraction processes.
- 6. Lack of quality control standards.
- 7. Lack of good safety and toxicity data.
- 8. Lack of well-established clinical trials.

Future

Advances in the areas of food technology, food biochemistry and the nutritional sciences (including nutritional genomics) are providing consumers with access to fresh, innovative and often supplemented produce with recognizable health benefits that previously were not available. New methods being used by the



functional food industry to isolate, characterize, extract and purify nutraceuticals from bacterial, plant and animal sources are resulting in decreased costs to the industry as well as providing new options for usage. Personalized healthcare is likely to lead to a proliferation of nutraceutical products. Companies will have to place strategic focus on technological breakthroughs to achieve results.

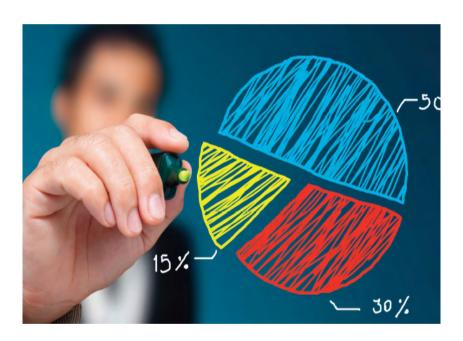
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Challenging Art: Forecasting



In the most complex and competitive Indian pharmaceutical market, it is tough to forecast both demand and sales. Since sales forecasting affects every department of the company, it has to be done meticulously. Read on to know the four most practical methods to follow while forecasting sales as discussed in a inclusive way by Prof. Parag Mahulikar.



CHALLENGING ART: FORECASTING

Forecasting is like trying to drive a car blindfolded and following directions given by a person who is looking out of the back windows.

- Anonymous

Forecasting is divided into two parts: (a) Demand forecasting and (b) Sales forecasting. In the most complex and competitive Indian pharmaceutical market, it is tough to forecast both: demand and sales.

For demand forecasting Jesse Werner gives us good advice saying "For most accurate forecasting forget your present volumes; start with the future trends of the economy, then mix in projections of market demands, and customer needs and then finally evaluate your own firm's prospects for expansion and growth."

Forecasting demand for a product is tougher than forecasting sales for a product as demand forecasting requires a lot of data which may not be easily available and after making it available it is complex to use and forecast. Demand for a new product could be forecast by 'test marketing' and / or conducting a 'prescription intension survey' among doctors.

Sales forecast affects every department of the company. And, hence it has to be done meticulously and accurately.



Fig. a Impact of Forecasting on Major Department

Once the sales forecast is made, production department gears up and makes all the necessary arrangement to produce hundreds of products as per the forecast and as required by marketing department on weekly or monthly basis. It has to ensure that sales does not suffer because of unavailability of products. Purchase department also rolls up its sleeves and makes procurement programs to supply every raw material to production department so that its production does not halt up. Purchase department works in tandem with inventory control and ensures that money is not locked up in unnecessary items and smooth supply of raw material is maintained. Logistics and Supply Chain management department arranges to and fro movements of finished products to every nook and corner of the country. Finance department makes arrangements for adequate money so that supply of raw materials and movements of finished products do not suffer. Human Resource Management also gets ready to recruit and train more employees, if required, to achieve sales target. Thus, sales forecast puts every department of the company on its toes.

If th forecast sale is achieved, then every department is happy that it lent support to achieve the target. However, if it's not achieved, then marketing / sales gets flak from all the departments besides top management. Knowing the importance of sales forecast, once a SCM head of a MNC approached us and asked us if we could train its sales force in sales forecasting as he was one of the affected persons in the company since he was making all the arrangements to carry finished products to every nook and corner of the country and only 70 to 80 percent forecast sales were being achieved by the company.

Let's deal more in detail in sales forecasting (for next year), which every pharmaceutical company does it every year and calls it 'budgeting exercise'. Average time taken by a company is three months to complete product wise budget for the next year. Most of the companies use their experience and expertise to forecast the sales and a few use certain techniques and software to project sales of every product. Sometimes a forecast is made by telling marketing & sales teams that 'management wants 15 % growth next year.' On what basis is 15 % decided is not known. In Indian market, one MNC was growing at the rate of 10 % to 12 % per annum and wanted its team to achieve 30 % growth next year. Of course, the MNC did not achieve the 30 % growth. However, marketing and sales team was under tremendous pressure.

For sales forecasting let's look at the following practical methods:

- I.Delphi Method
- 2.Bottom Up Method
- 3. Regression Method
- 4.CAGR Method

I. Delphi Method:

In Delphi method experts are consulted about the market growth, therapeutic class growth, impact of new products and government policies etc. to get good idea about the market and get a base for forecast. In this method, if an experienced person talks to experts he can add better value to forecast, as he would get better perceptions of the market and can use the discussions fruitfully for forecasting sales based on his experience.

2. Bottom Up Method:

In this method, marketing department asks sales to prepare forecast from the lowest rung of its ladder viz. medical representative or professional sales officer. The MR/ PSO looks at his achievement product wise in his territories and quotes some figures product wise keeping something under his sleeves. He will not give the real potential that he can achieve naturally. Similarly forecast is collected from frontline manager, regional manager, zonal manager and finally from all India sales manager.

Marketing people work out forecast for each product in each area based on some statistical techniques and performance of economy. Then, both the forecasts are dovetailed in an annual meeting where marketing and sales people make presentations about their forecasts and bases for forecast. Such meeting lasts for three days wherein the dovetailing of forecast is done. Once the forecast (targets)



are accepted by sales people, then they are frozen and marketing inputs are given to achieve the forecast (sales).

When marketing people make the forecasts they can use very simple statistical methods as regression and CAGR of various methods available to them.

Before we discuss the above methods (Regression & CAGR) in detail, let's keep the following points in mind:

- 1. Total pharmaceutical market (size)
- 2. Its growth rate
- 3. Performance of various Therapeutic Classes (TCs) & their size
- 4. Share and rate of growth of each Therapeutic Class
- 5. Number of brands in each Therapeutic Class
- 6. Top 5 brands expanding each Therapeutic Class market, their share and their growth rate
- 7. Brands losing market share, their share and growth rate
- 8. Your brand's sales, market share and rate of growth
- 9. Share of new brands in each Therapeutic Class

3. Regression Method:

Regression, simple & multiple, are statistical methods useful to forecast the sale based on the past data. Before simple regression is used, keep in mind the following points:

- I. Plot the given data. If you get a straight line indicating linear relationship between the two variables (year & sale) use the regression.
- 2. Change the years to 1, 2, 3, 4, 5, etc. from year 2011, 2012, 2013, 2014, 2015.
- 3. If you have 10 years of data, divide it into two parts viz. first five years and second five years.
- 4. Use current five years data as it is reflects the market reality.
- 5. Use SPSS or Excel to do regression analysis.

Let's take a real case for regression analysis. Let's look at sales of Cipla for the past 10 years.

Year	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Sale (Rs. Crore)	2891.36	3438.24	3997.90	4960.60	5359.52	6331.09	6977.50	8202.42	9456.90	10131.78

Source: Ace Analyser

The first five years data is from 2006 to 2010 and current five years data is from 2011 to 2015. We would work on the data from 2010 to 2014 and project the sake for 2015 and check the accuracy of our estimate as the 2015 sale is given as Rs.10131.78.

The graph of the data from 2010 to 2014 indicates almost a straight line except a slight dip in the year 2012. There is no erratic pattern of sales and hence we can go ahead with regression model.

The model is Y = a + bx

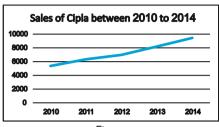


Fig. a

Where Y is dependent variable (Sales) and x is independent variable i.e. year b is a regression co-efficient.

When we put the data into SPSS, we get, the following tables:

Model Summary^b

					Std. Error				Change Statistics					
Model		R	Adjusted R	of the	R Square	F			Sig. F					
	R	Square	Square	Estimate	Change	Change	df1	df2	Change					
1	.993ª	.987	.982	213.12130	.987	223.084	1	3	.001					

a. Predictors: (Constant), Year

Model Summary^b

				Std. Error	Change Statistics				
Mod		R	Adjusted R	of the	R Square	F			Sig. F
el	R	Square	Square	Estimate	Change	Change	df1	df2	Change
1	.993ª	.987	.982	213.12130	.987	223.084	1	3	.001

b. Dependent Variable: Sale

Mod	lel	Sum of Squares	df	Mean Square	F	Sig.
1	Regression	1.013E7	1	1.013E7	223.084	.001ª
	Residual	136262.065	3	45420.688		
	Total	1.027E7	4			

a. Predictors: (Constant), Year

b. Dependent Variable Set

Coefficients^a

Unstandardized Coefficients			Standardized Coefficients			С	orrelations		
Model		В	Std. Error	Beta	t	Sig.	Zero-order	Partial	Part
1	(Constant)	4245.659	223.524		18.994	.000			
	Year	1006.609	67.395	.993	14.936	.001	.993	.993	.993

a. Dependent Variable: Sale

The Model Summary table above indicates that R=0.993 and Adjusted R square = 0.982. This means that 98.2 % variation in independent variable (Year) is well explained by the model and hence, the model is good. The ANOVA table gives us significant value =0.001, which is less than 0.05, indicating that the model built is significant at 5 % level of significance. Since the model is good and significant, we can use it to predict the sale in 2015.



From coefficient table we get, a = 4245.659 and b = 1006.609. We put these values of a and b in the following equation. Value of x will be 6 as we have 5 years data and we are estimating sales for the 6th year (2015).

```
Y = a + bx

Y = 4245.659 + 1006.659 \times 6

= 4245.659 + 6039.954

= 10.285.613
```

The estimated sale is Rs. 10,285.613 and actual sale is 10131.78.

```
Thus, we get efficiency of our estimate as Efficiency = Estimated sale / Actual sale = 10,285.613/10,131.78 = 1.0158.
```

It means that we, by regression method, have over estimated sale of Cipla for the year 2015 by 1.58 %. It's a very good accuracy.

Now we will estimate sale of Cipla for 2016. For this estimation, we will use data from Cipla's table from 2011 to 2015. Applying regression for the same data we get estimated sale for 2016 as Rs.11,243.468. The regression model, as we know, is over estimating sale of Cipla by 1.58 %. Applying this correction to the projected sale of Rs.11,243.468 we get actual estimated sale for 2016 as Rs.11,068.5844.

Similarly, let's take sale of Colgate Palmolive (India) Ltd. which is as follows:

Year	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Sale	1295.14	1473.38	1694.81	1962.46	2286.12	2693.23	3163.81	3578.81	3981.94	4162.29
(Rs.Cr)										

Source: Ace Analyser

Putting data from 2011 to 2015 in SPSS and working out regression, we get a = 1857.616 and b = 427.722. Substituting these values in the equation Y = a + bx, we get estimated sale of Colgate for 2016 as Rs.4418.332. Here, the Efficiency of the estimate = 4418.332 / 4162.29 = 1.0615%. This indicates that Colgate's sale for 2016 is over estimated by 6.15%.

If we can estimate sales 90 % accurately, it can be of great help to us. In both the cases—Cipla and Colgate, we do not know the marketing inputs provided by the companies and still we could estimate the sales accurately. This method of regression will be of great help in practice. If we know the marketing inputs we can use the multiple regression.

4. CAGR Method:

This method is compound annual growth rate method. This gives us rate of growth of product or company sales. The formula for CAGR is as follows:

$$A = P(I + r/100) n-I$$

Where, A = Latest year sale

P = base (first) year sale

R = rate of growth

N = no. of years of data

The formula could be solved in the following easy four steps.

Referring to Cipla's table, we get Sales for 2011 = Rs.6331.09 and sale for 2015 = Rs.10131.78

For the data from 2011 to 2015, sale of 2011 is base year sale and that of 2015 is the latest year sale. Substituting these values in the following formula we get,

Step I: latest year sale/ base year sale = 10131.78/6331.09 = 1.6003

Step 2: take 4th root (since we have five years data) of 1.6003 = 1.1247

Step 3: 1.1247 - 1 = 0.1247

Step $4:0.1247 \times 100 = 12.47\%$

This indicates that Cipla's growth rate between the years 2011 to 2015 is 12.47 %

Applying this growth rate to its 2015 sale of Rs.10131.78, we get estimated sale for the year 2016 as Rs.11,395.21

Similarly, the rate of growth of Colgate is worked out as follows:

Step I: latest year sale / base year sale = Rs.4162.29/2693.23 = 1.5455

Step 2: 4th root of 1.5455 = 1.11497 = 1.1150

Step 3 : $1.1150 - 1 = 0.1150 (0.1150 \times 100 = 11.50 \%$ rate of growth of Colgate between period 2012 to 2016)

Step 4: 1.1150 X 4162. 29 = 4640. 95 (Estimated sale of Colgate in 2017)

The two methods discussed above—Regression and CAGR- are simple and practical. Companies should follow them and work out a base forecast. The forecast, thus worked out, should become the point of discussions and the experienced managers should now add their expertise, wisdom and market insight to fine tune the forecast. Such forecasts will help all the concerned departments to work in sync and achieve it.

About the Author

Prof. Parag Mahulikar is Dean and Senior Professor of Marketing at IES Management College and Research Centre, Bandra, India and also a Management Consultant. He has over 30 years of diverse experience of working with several 'Fortune 100' Indian companies in the field of Marketing and Marketing Research. He has taught in various prestigious management institutes in and outside Mumbai. He has been conducting executive development programs for senior managers and executive directors for the last 25 years. He also conducts Faculty Development Programs in 'Research Methodology and Data Analysis' for professors of management schools.







Salvaging Underperforming Brands



For every organization it is very essential to have a Brand Planning process in place. An effective brand planning process ensures a higher number of performing brands for the organization. Read on to get deeper and detailed insights on the management of underperforming brands as discussed in an inclusive way by Mr. Uday Lawate.



SALVAGING UNDERPERFORMING BRANDS

Every organization has its fair share of successes and failures. It is very essential for every organization to have a Brand Planning process in place, which over a period of time has to be fine-tuned to ensure a higher number of high performing brands and a lesser number of underperforming ones.

While discussing underperforming brands, one cannot be prescriptive. Ideas have to evolve based on customer responses and capabilities within the organization to either respond to a situation or create a desired superlative response.

There can be many reasons why one may choose to label a brand as underperforming. To enumerate a few, the top line numbers could be consistently missed or the bottom line could always be under pressure. It could also be that the potential is not tapped to the fullest or competitors are doing much better resulting in lower than expected market share. It could also be that the field is spending a lot more time than what was planned and hence, draining vital resources which cannot be quantified immediately in value terms.

Head office

Market Assessment
Planning
Planning

Head office

Execution
Interdepartmental
coordination

Fig. a

Assuming any of these reasons to be true, we need to identify the root cause of this under performance. Is this due to poor planning, poor execution or failure of both – planning and execution? These can be at the level of head office or the field or both. More often than not, it is the failure of planning rather than execution, as clear execution plans are supposed to be part of the planning. Pitfalls in execution are to be anticipated with certain assumptions and here is the role of plan B.

Typical causes of Under Performance Market Assessment

- I. Changed Market Scenario: A new option comes in or the treatment patterns change, leading to change of choice of doctors and a lower/higher preference for the brand.
 - •Co-Prescription of H2 Receptor Antagonists with NSAIDs.
 - •Combination therapy in anti-hypertensive and anti-diabetic therapies, leading to poor chance for single drugs.
- 2. Forecast: Failure to anticipate events that can potentially have either positive or adverse impact on the brand.
 - Changes in treatment algorithm.
- 3. Scalability: From the planned quantity to the unexpectedly high level.



- 4. Inadequacy of the range required e.g. only oral dose when injectable and oral are desired, plain vs. combination, typical of India is also a lower dose than that recommended in western studies (especially anti-hypertensives).
- 5. Pricing issues: DPCO, NPPA
- 6.Inadequate attention to regulatory issues or ignorance of (deliberately overlooking) the likely issues of safety even though minimal.
 - •Ban on certain FDCs.
- 7. Sub-optimal launch: Inadequate promotional budgets, lack of training.
- 8. Safety issues: Coxibs
- 9. Quality issues with either the product or the packaging:
 - Tablet does not retain its form, color of liquid or injectable is not as desired, protein or food supplements turning sticky (even Cadbury's had issue of worms)
 - Poor maintenance of cold chain vaccines turning opaque.
 - •Outer carton gets damaged in transit, or looks shabby when samples are given.
 - •Bottles break due to poor shippers.
- 10. Supply chain deficiency: Stocks made without taking into consideration the likely off take, poor distribution ending up low stocks in high selling areas and vice versa.
- II. Lack of enthusiasm: Deficiency in planning at the field level right from selection of target customers, to efforts vs. return expected.
- 12. Poor identity of the brand in terms of a clear STP.
- 13. Poor response of doctors owing to raised expectations not being fulfilled.
- 14. Product knowledge shared by field force not enough to adequately address questions.
- 15. Lack of clarity on the concept 'too early for its time'
- 16. Clear creation of need for the product.

The Amlodipine launch by Pfizer in the 90s vs. Sitagliptin by MSD a decade later can be cited as examples of difference in response. The case of Coxibs going bust or the example of Losartan getting a six month extension of patent due to pediatric exclusivity can be examples of the role of regulatory agencies.

Hence, one or more of parameters listed above will need to be acted upon. Market assessment has to be kept independent of the target. It has to consider only a set of parameters which will help identify the potential that the opportunity presents.

As we all agree, target should be stretched but achievable. Yes, an aspirational value has to be set a few notches higher and has to be evaluated and rewarded separately. At the same time, the field notion of under promise and over deliver is also not a great approach. As Jack Welch says, a top down or a bottom up process alone will not work. It has to be evaluative, honest, transparent and data based approach. It has to be dialogue oriented process and only TRUST has to be the guiding force. If not, here is the down side – great prescription flow with stock outs and prescriptions not honored, or a deluge of stock with not enough prescriptions. The product bombs!

Sanjiv Mehta of Hindustan Unilever brought in a new perspective when he said "if the per-capita consumption in fabric conditioner was to increase to the same level as Vietnam, the market in India for fabric conditioners would be 40X larger."

What is specially expected in managing an underperforming product is the role of doctor and patient centric data. Analytics on parameters listed below have to be a great start to the decision making process:

- •Sales over months and quarters
- Performance and growth
- New prescriptions
- New prescribers
- •Degree of achievement of treatment goals
- Patient compliance
- •Target doctors met
- Frequency of effort

Evaluation of Performance

Evaluation of performance on a set of predetermined metrics needs to be conducted to measure the degree of success. The data for this evaluation has to come from the stakeholders such as doctors, patients, care givers, dieticians, patient counselors, stockists, retail chemists, hospital pharmacies and so on. Perspective of the sales team too needs to be given due consideration. A close look at the Brand Plan, its implementation and feedback need to be considered in order to take next steps.

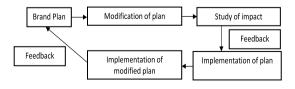


Fig.b Evaluation of Performance



Without an objective assessment of the root cause one of the following is certain:

- I. A brand is given up.
- 2, Blame game is set off without any action plans.

Crying over spilt milk is useless. One should aim to salvage what is left, nurture and augment it to achieve what we want. Is it the packing, promotion, price, availability, clarity in terms of tangible benefits. Do the costs need a relook to improve profitability?

With a thorough study of the whole picture, the third option can pan out in the form of a clear action plan with a road map to set up a recovery

About the Author

Mr. Uday Lawate has 29 years of experience in Pharmaceutical Marketing and Sales Consulting across major geographies and with many MNCs. He has a track record of creating major brands across therapy areas, three of which have been number one all India. He has also institutionalized first in-house developed CRM system in Indian pharmaceutical scene and has improved productivity and quality of sales through effective application of analytics.





Navigating The South Korean Pharmaceutical Market



The South Korean pharmaceutical industry is all set to achieve great heights as a result of high quality services and universal healthcare based on choice. Read on to get detailed insights on the dynamics of South Korean pharmaceutical industry as discussed in an inclusive way by Ms. Shreya Pathare.



'NAVIGATING THE SOUTH KOREAN PHARMACEUTICAL MARKET

South Korea has been termed as the Asian Tiger economy and has managed to maintain its speedy growth levels, low debts and resilience to financial crisis. South Korea's high growth rate has been consistent and is the fastest growing developed economy in the world. With the involvement of lot of international players in the country, the business scenario has improved considerably over the years. The pharmaceutical industry in the region is all set to achieve great heights as a result of high quality and universal healthcare based on choice.

Dynamics of the South Korean Pharmaceutical Industry

The pharmaceutical market in South Korea is the 13th largest in the world and 3rd largest in Asia. The market was valued at USD18.6 billion in 2016 and is expected to grow to USD20.4 billion by 2020 with a CAGR of 2.4%. 80% of the total pharmaceutical market is projected to be captured by prescription drugs due to growing elderly population and prevalence of chronic diseases.

The generics market in the region has increased from USD3.5 billion in 2008 to USD5.8 billion in 2015 through a CAGR of 7%. With many drugs set to lose patents by 2020, the generics market in South Korea is going to witness considerable growth. The spending on healthcare reached USD101 billion which is about 7.4% of the GDP. However, this current spending is very low for any developed country.

South Korea has around 47 multinational players including top multinationals like Pfizer, Sanofi, GSK and Novartis. Prescriptions from these players lead the pharmaceutical market in the region. Having said that, South Korea has approximately 250 local pharmaceutical manufacturers with major focus on generics and OTC drugs.

The country is also increasingly focused on making its mark in the biosimilars space with the Ministry of Knowledge and Economy setting a target to achieve 22% of the biosimilars market share by 2020. In fact, Dong A, a top local drug maker has already received US FDA approval for its super-bacteria antibiotic Sivextro.

The region had about 467 drug candidates with 250 NMEs, 200 IMDs (incrementally modified drugs) and 25 biosimilars under development by Korean pharmaceutical drug makers by the end of 2012.

The region is also actively pursuing therapeutic-specific research with leading focus on oncology (18.9%) followed by diabetes (9.7%). Quintiles Korea is conducting numerous studies on oncology and hematology followed by research on anti-infectives, immunology and cardiovascular therapy segments.

The increasing elderly population due to low fertility rates as well as due to non-communicable and chronic diseases like cardiovascular conditions, obesity, cancer and diabetes, has sustained the demand for pharmaceuticals in the region.

Growth Facilitators

Pharmaceutical Ingredients

The growth of the pharmaceutical ingredients in South Korea and in turn the

pharmaceutical market is driven by the increase in adoption of biologics and biosimilars. South Korea in addition to China, India and Taiwan, contains great concentration of active pharmaceutical ingredient (API) suppliers (76%) with large number of companies vertically integrated and capable of supplying to the world's highly regulated pharmaceutical markets. Data from Thomson Reuters shows that 12 South Korean API companies have at least one US DMF (Drug Master File) and at least one API determined to be available commercially. As compared to other Asian markets, South Korea has grown considerably over the last decade in terms of both size and expertise. As a result, companies are frequently turning to these nations in search of API suppliers and potential partnerships. The signing of CEPA (Comprehensive Economic Partnership Agreement) with South Korea is likely to give a boost to the bilateral trade between the two nations especially in the API sector.

Local Innovation

A strong talent pool has led to effective outcomes in terms of innovation in product development. Reports indicate that a total of 19 new drugs were developed locally in the region between 1999 and 2012. An example would be of Cartisem, developed by Medipost based in Seoul, and approved in 2012. Cartisem is the world's first approved genetic stem cell drug to treat degenerative arthritis. South Korea has also witnessed innovation with incrementally modified drugs (IMDs) and biologics including biosimilars. An innovation of this kind coupled with strong talent pool can help pharmaceutical companies, both local and multinational to flourish in the region.



Fig. a Growth Facilitators Source: Interlink Knowledge Cell

Healthcare Spending and Medical Access

97.1% population in South Korea is covered by the National Health Insurance (NHI) plan through compulsory contributions to the plan. Population over a certain level of income must pay to the plan, while Medical Aid provides access to



healthcare services for the not so privileged. The healthcare system in the region is quite unique and is entirely based on choice with customers choosing between a universal plan that covers employees and relatives, long-term medical insurance plan or the Medical Aid plan. The national expenditure on healthcare in 2011 was USD91 billion and is estimated to rise because of expanding NHI coverage and an aging population. This spending on healthcare along with medical access would thus, enable the sustenance of the pharmaceutical players in the region.

Free Trade Agreements

The signing of Free Trade Agreements with the US, Europe and India have improved the intellectual property rights framework in the region and has made the South Korean pharmaceutical industry more attractive for foreign investment.

Clinical Trials

The region, over the years, has become a major destination for clinical trials because of good medical facilities, sufficient patient pool with supportive Government policies. South Korea constitutes only 2.5% of the world's clinical trial market but is turning out to be a main hub for Phase I and Phase II clinical trials.

Government Initiatives

To reach the goal of developing 10 new global drugs and creating 12 global companies by 2020, the Government is trying to boost the pharmaceutical market with a fund for R&D, tax deductions for R&D costs, promotion of mergers and acquisitions, training of manpower and creating and sustaining a national pharmaceutical company to compete globally. The Government has also identified and designated 10 'research-driven hospitals' in 2013 by the act to substitute health technology (HT) R&D in university hospitals. Also, the Government has enacted regulations to ensure fair trade and commercial practices within the industry. The Korean Pharmaceutical Affairs Law (KPAL) strictly regulates the advertising of OTC drugs and prohibits the sharing of information to the public about prescription drugs. However, this body does not prevent the advertising of prescription drugs for infectious and chronic diseases. KPAL additionally sponsors awareness programs in the region.

Challenges Encountered

With the growth drivers, the pharmaceutical industry in South Korea faces its fair share of challenges with the likes of strengthening regulations, forced lowering of prices of drugs and emphasis on generics produced after expiration of patents.

The local manufacturers tend to suffer with the enactment of intellectual property laws, finding it hard to compete within the new business scenario. Most of them will be devoid of any support from the Government for not being engaged in R&D. As a result, the generics pricing will decrease further. Litigation will increase considerably as domestic manufacturers will try to fight patents and price cuts. Competition from China and India will increase for manufacturers of generics and the alleged inclination towards domestic pharmaceuticals will also reduce.

The pharmaceutical market in the region remains undefined for multinational players. The existing policy of having price cuts is leading to differences between the

drug makers and the Government over fair and correct pricing of the products.

The spending on pharmaceuticals has been on a high for many years with medicines quickly approved into a huge reimbursable list with no cost-value considerations in the past. As a result, the current delisting including retroactive reassessments is taking away profits.

The restructuring of the pharmaceutical industry in the region as envisioned by the Government is based on two facts: containing cost and ending illegal practices. Lengthy and arguable negotiations have given rise to delays in launching of drugs.

Even with the freedom to choose healthcare services and practitioners, the satisfaction of the people with the health system in South Korea is low because of high expenses and long waiting lists for treatment. With co-payments between 10%-15%, the treatment is not entirely free at the point of delivery. Most of the specialist doctors are private with healthcare centers providing only basic primary care. The country is also witness to several regional disparities which create a number of challenges. These factors are prompting the population of South Korea to seek treatments abroad thus, proving to be a drain for the Government's finances.

Looking Ahead

South Korea has all the right factors to sustain the growth of pharmaceutical industry. With strong support from the Government and implementation of free trade agreements, there will be a positive impact on the pharmaceutical and healthcare market through intellectual property protection, access to the single-payer Government system and decrease in trade tariffs. On the other hand it will be extremely important for the local manufacturer to keenly look at pricing and reimbursement reforms and also be fully ready to provide strong clinical and economic data in order to reason out the pricing and access to market. Looking at the bigger picture, the pharmaceutical industry in South Korea remains positive and all set to flourish in the years to come.

About the Author

Ms. Shreya Pathare, Post Graduate in Microbiology, is currently working as an Associate Consultant with Interlink Marketing Consultancy Pvt. Ltd. She is successfully assisting in various research-based consultancy projects and has contributed in writing project reports and developing content for write-ups on various subjects and for presentations with active contribution to digital marketing.







New Management Challenge: Financial Transparency



It is very challenging for the Private & Public listed corporate entities operating in the healthcare sector to comply with the new compliance requirements under the Companies Act on the subject of Internal Financial Controls. Read on to get detailed insights on internal financial controls as discussed by Mr. Huzeifa Unwala.



NEW MANAGEMENT CHALLENGE: FINANCIAL TRANSPARENCY

Growth of healthcare sector in India is no more an item on the agenda of Boards as that is a given, rather effective compliance with legal and regulatory framework and protection of reputation is considered as most critical to the growth and sustainability of the healthcare story. India is slated to be amongst the top three healthcare markets by 2020, however, the underbelly of the Indian healthcare sector continues to be plagued with several fraudulent schemes and activities that bring disrepute to the sector.

Government agencies and several leading bodies have published statistics that indicate un-ethical and un-healthy practices in the Indian healthcare sector. For example; bribes for referrals, fabricating false medical reports, over charging of consumers, inventory channel pushing by Corporates, health insurance frauds, organ rackets, etc.

Transparency International reported that healthcare is amongst the top most corrupted sectors in India. In light of this, it would be very challenging for Private and Public listed corporate entities operating in the healthcare sector to comply with the new compliance requirements under the Companies Act on the subject of Internal Financial Controls.

Corporate Governance

The 2013 Companies Act marks a major step towards raising the bar on Corporate Governance in India. The Companies Act has re-emphasised the importance of a robust internal controls environment by introducing the term 'Internal Financial Controls', and by casting specific and onerous responsibilities on the Board, Audit committee, Executive Management, Independent Directors as well as the Auditors. In particular, section 134(5) of the Companies Act, 2013 requires the Board to include an statement as part of the Directors responsibility ensuring implementation of adequate internal financial controls (IFC), adherence to policy and procedures adopted by the company with an objective of orderly and efficient conduct of its business, safeguarding of company's assets, prevention and detection of frauds, accuracy and completeness of the accounting records and timely preparation of reliable financial information. Further, the section prescribes penalties of up to Rs.25 lakhs and imprisonment of 3 years for contravention of these provisions. IFC provisions have noble intentions to align our country to global best practices in governance, restore the faith of investors and consumer protection, however, are difficult to comply 100% in spirit given the business realities in the country. The IFC provisions are born from the fear of repeat of Satyam and other similar fraudulent financial reporting scams in the recent history of Corporate India. As a result, it appears that the law makers have embarked on a massive hunt for tracking down Corporate Control Deficiencies.

Reality

India has the largest population of listed entities. In addition it appears that the IFC applicability extends to private companies as well. Healthcare sector in India has over 500 listed companies and thousands of private companies. It seems an



improbable monitoring task on hand and therefore Indian Corporates are often tempted to apply short cuts knowing fully well that there is no regulatory oversight thereby adopting a 'tick' approach to demonstrate compliance on paper. To safeguard against such practices Auditors have to mandatorily certify the adequacy and operative effectiveness of internal financial controls over financial reporting under the provisions of the Companies Act, 2013.

Step Ahead

IFC is a significant step ahead of the Clause 49 that requires certification of the CEO and CFO on controls over financial reporting and CARO that required auditors to comment on the adequacy of internal control system and whether there is any continuing control deficiency that needs to be corrected. IFC is one glaring example where law abiding Indian Corporates are struggling to find ways of complying with section 134 (5) of the Companies Act, 2013.

Majority of the Indian Corporates who have immensely benefitted from their controls journey over the years and who intend to comply in letter and spirit are looking at IFC as a one-time investment to refresh their repository of risk and controls. IFC shall certainly improve transparency by highlighting control related disclosures but does it mean that actual evaluation of control as required by the spirit of law shall be effectively implemented – going by our previous corporate history and disclosure standards chances are rarest of rare. Companies that take internal financial controls seriously, generally design and implement well defined policies, guidelines, Standard Operating Procedures (SOPs), authorization and approval procedures and high technology intensive processes. Due emphasis has to be given to financial closure controls that ensure accuracy and completeness of the accounting records, timely preparation of reliable financial information, prevention and detection of frauds and errors and safeguarding of the assets.

Global IFC/SOX Experiences

Published information suggests that when the US – SOX was implemented in late 2004, Section 404(a) required management evaluation and reporting on ICFR, and Section 404(b) required an independent audit of ICFR effectiveness. As a result, the internal control information for investors substantially increased. Over time, the proportion of US public companies disclosing material weaknesses declined substantially. Further, majority of the deficiencies were not reported to the Audit Committee.

US opinion makers generally agree that despite high initial costs of designing and implementing sustainable internal control systems, evidence shows that it has proved beneficial. Markets have been able to use the information to assess companies more effectively, managers have improved internal processes, and the internal control testing has become more cost-effective over time [as per Forbes/HBS working knowledge March 2014].

In contrast to mandatory compliance in India, the UK code requires firms listed on the main exchange to report how they comply with listing rules that include voluntary application of the Turn bull Guidance on internal control in the Combined Code. Listed firms can comply by disclosing, with or without independent auditor assurance, or by explaining why they do not comply, and let users assess the quality of non-compliance.

Key advantage of 'comply or explain' is that it allows individual firms to conduct cost benefit analysis regarding whether, and how, to comply over time and to avoid costs when they believe net benefits would be small. It therefore encourages standard setters for internal control criteria and auditing to develop cost-effective standards. A disadvantage of 'comply or explain' is that firms with poor internal controls may use cost-benefit concerns to avoid auditor involvement in internal control disclosure where it may be most beneficial.

Conclusion

The Institute of Internal Auditors (IIA), USA in its various publications on the subject of Control Self-Assessment (CSA) states that CSA is a relevant approach to gathering internal control information in today's environment, and it can effectively augment internal control initiatives. Key stakeholders strongly agree that from a cost benefit balance CSA could be the most suited and preferred option for meeting the Companies Act, 2013 and other regulatory and compliance requirements. They are also of the opinion that CSA is relevant in today's times and that it is an absolute necessity in case of multi-product and multi-region companies.

The first few years of IFC would be hugely difficult—particularly for corporates, regulators and practitioners, as they would have to navigate through emerging practical difficulties, however, with techniques such as CSA, the process can be simplified. Global survey results reveal that SOX has increased investor confidence and reduced fraud potential. Therefore, intangibles far outweigh the tangible compliance costs involved and now that IFC is legally mandated Corporates should use the opportunity to elevate their governance practices.

About the Author

Mr. Huzeifa Unwala has over 18 years of composite experience in servicing International, large and medium sized clients in the areas of Management consultancy, Business Advisory, Fraud Investigations, Internal Audits, IT Advisory, SOX/ Clause 49 implementation assistance and Enterprise wide Risk Management. Prior to founding NMAH he was a Partner & National Head of Risk Advisory Services practice of BDO in India and was also a Practice Director, Business Risk Services at Grant Thornton in India. He has made several notable contributions to professional bodies like IIA, ICAI, BCAS, ISACA, CII, Indian Audit & Accounts (C & AG) and other professional forums. He is a prolific writer and speaker and has spoken at more than 50 professional seminars, events and industry forums.







A Boost of Health and Energy



The awareness of the fact that food can provide benefits other than just. satisfying hunger has led to the boom of the functional food and beverage market in the world. Read on to get deeper and detailed insights on the growing segments of functional beverages as discussed in an inclusive way by Ms. Ankita Dhekne.



A BOOST OF HEALTH AND ENERGY

The focus on health has increased a lot in the past few years. The attitude of people in general has shifted more towards proactive and preventive care rather than passive treatment or reactive care. In line with the shift towards proactive and preventive care, the consumer buying pattern of food and beverages has also undergone a major shift. Consumers all over the world have started adapting healthier food and beverage options in their daily lives. The awareness of the fact that food can provide benefits other than just satisfying hunger has led to the boom of functional food and beverage market in the world. Among the functional food categories, functional beverages are currently more active across the world as compared to other categories.

The functional beverages market of US was pegged at USD27 billion after it grew by 7.4% in 2013. Energy and sports drinks accounted for 82% of the total functional category in 2013, although the protein segment experienced more growth.

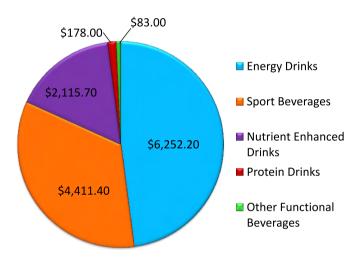


Fig.a - Estimated Sales in US 2012 2013

India is also fast catching up with the growing health food and drinks market of the world. The non-alcoholic beverages market in India was estimated to be around USD5 billion (Rs.33,318 crore) in 2015, according to a report by the Indian Beverage Association.

In the beverage segment, health drinks; mostly malt based (such as Horlicks, Bournvita, Complan, etc.) are usually widely consumed by young children, although having said that many new health drinks are coming up in the market targeting adults. In case of energy drinks, adolescents are the major consumers as compared to other categories. The health drinks market in India was pegged at Rs.4000 crores (90000 tonnes) and is expected to reach Rs.8000 crores by the end of 2016. India is one of the world's largest malt-based health drinks market almost 22% in the world's total retail volume. The energy drinks market in India is estimated at Rs.700 crores and is expected to grow at a CAGR of 20-25%.



The Malt beverages are of two types, white beverages (powders) which constitute around 65% of the share and brown beverages (powders) which constitute around 35% of the market share. These health drink powders are consumed with milk or as milk substitute & nutrient boosters. This segment is mainly targeted towards children.

The Energy beverages originated in Japan in the 1960's to help the working class people cope with long working hours. It then made its way to America in 1997 and is now gaining a grip in the United Kingdom, Brazil and India.

The health drinks market in India is already well established but the energy drinks market although at a nascent stage is growing rapidly. Currently the energy drinks market in India is focused in the urban areas and has not yet penetrated in the rural segments.

Growth of Health and Energy Drinks Market in India

The health and energy drinks have captured the shelves much faster than any of the beverages (carbonated/non-carbonated drinks) in the Indian market. The energy drinks are consumed more by adolescents as these drinks claim to provide energy, improve performance and endurance. The hectic and stressful work life, urbanization and increasing socialization is pushing the Indian consumers towards energy drinks which are non-alcoholic caffeinated and sweetened beverages. This along with increasing disposable income, higher purchase parity among young adults is propelling the sales of energy drinks. Also, increasing health consciousness among the youngsters is pushing the sales of non-alcoholic, caffeinated beverages and sports drinks.

The health drinks category is further expanding through condition, age & gender specific products. The companies leading in malt based children's health drinks segment are expanding the malt drinks segment to adults as well. The expansion can be observed mostly in the women's health segment eg. Women's Horlicks, ActiLife (Cadila) etc. Apart from this, many companies are exploring new segments of health drinks such as healthy juices, combining probiotics and fibers with juices or water, specialized drinks or formulae for diabetics and other conditions.

With India being a young country, it is one of the fastest developing consumer markets for products targeted towards youngsters and young adults, mostly belonging to upper middle class. This audience is ready to explore new products as well as financially they are ready to spend on health & energy drink products. This is definitely going to aid the growth of beverage industry.

Health and Energy Drink Brands in India

In India as well as in world, Red Bull is the leading brand in energy drinks segment. In India, Red Bull GmbH had an off-trade value share of 69% during 2013. Some other players in this category are Coca-Cola, PepsiCo, Monster Beverages, Hector Beverages, Bisleri, Dabur, XXX etc. In the malt based health drinks category, Horlicks (a brand of British pharma company GSK) is the leading brand valued at around Rs.3000 crore. Other top brands in malt based health drinks category are

Bournivita (Kraft-Cadbury, Mondelez International), Complan (Heinz), Nutramul & Pro (Amul India). Some of the players in other categories of health drinks are Amway International, GSK (Horlicks), Wockhardt (Proteinx), Nestle, Herbalife etc.

Emerging Trends in World Functional Beverage Category Dairy & Plant-based Beverages

Recent years have seen a surge in the demand for plant based foods. Dairy and plant based beverages will see upsurge in this year, with more and more companies spawning new products in this category. The rise in the demand for plant based foods is due to the reason that the consumers like the concept of these foods offering key vitamins, minerals and other nutrients in beverage format. Also, there has been resurgence in the demand for dairy products as dairy fat is no longer considered bad for health.

Reduced Sugar & Weight Wellness

Many companies in the industry are coming up with products that are low in sugar, but high in energy. This shift towards the consumption of less sugar is due to the rising interest in healthy foods. For example, consumers prefer natural cane sugar over artificial sweeteners in foods as well as drinks.

Protein

Protein has now been embraced due to increased awareness among people with respect to the need to include it in their diet on a daily basis. People now are also actively endorsing protein in connection with managing a healthy weight. The protein and energy drinks are widely used among sport players and youngsters going to gym and who desire to have a muscular body.

Naturally Functional

Naturally functional foods are those Foods/Ingredients that contain components which are naturally beneficial to our health i.e. they are naturally rich in nutrients and there is no need to fortify them such as, Soy milk, Almond milk etc. It's also interesting that companies are trying to combine protein drink concepts with energy drinks. As a result, many countries are observing a decline in the sales of artificial juices and smoothies along with an increase in the sales of natural juices, coconut water which are natural and low in calories along with being naturally sweet.

Meal Replacement Drinks

Although it has been well established that we should have wholesome and nutritious meal in order to stay healthy and fit, in today's fast paced lifestyle people don't find time to cook and/or to eat wholesome meal. So the meal replacement drinks pose a good option for such people as they get their daily nutrient from the drinks and it helps them maintain their health even in their hectic lives.

Future

Many new companies are venturing in this niche segment of functional beverages considering its growth in India. The perception of beverages is further changing with people considering it as a meal rich in nutrients and not just as an adjunct to meals.



During the last 3-4 years many food and soft drink companies have been prospering in the segment of functional beverages Energy Drinks - JK Ansell (Raymond Group Company), Monster Energy Drink, K G Functional Beverages, Bisleri International; Juices, Flavoured milk - Dabur, Amul, Pepsico etc.

Owing to the health awareness of consumers, companies are looking at functional and healthier beverages which contain lesser calories and lower levels of caffeine, nutrients from natural sources. With the healthier variants of beverages coming up consumers are sure to be inclined to buy these beverages more and thus aid the growth of this sector.

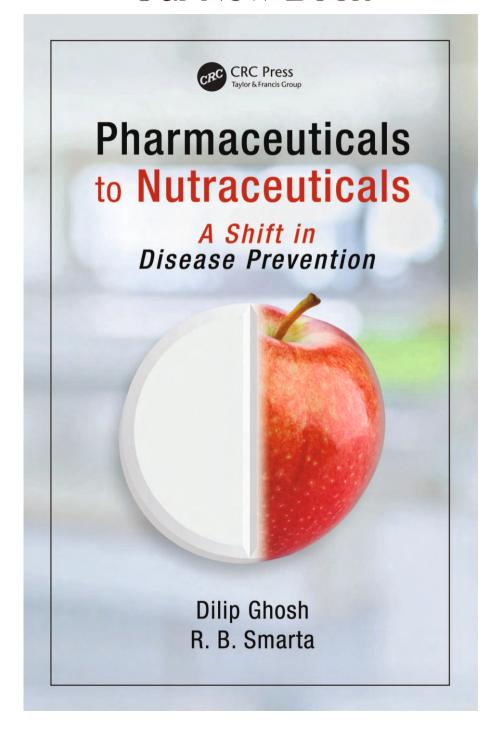
With the health drinks expanding and energy drinks gaining their foot, the beverage market is expected to witness a huge growth in emerging countries in the coming years.

About the Author

Ms. Ankita Dhekne, Associate Consultant, Interlink Marketing Consultancy Pvt. Ltd., is a Post Graduate in Nutraceuticals. She has been successfully assisting in various Research-based Consultancy Projects and actively contributing to various marketing activities as well. She has contributed in writing project reports, developing content for company's presentations, articles and other publications. She has a whitepaper and a few articles to her credit.



Our New Book



PHARMACEUTICALS TO NUTRACEUTICALS: OVERVIEW

This book on 'Pharmaceuticals to Nutraceuticals: A Shift in Disease Prevention' is a text/reference book connecting various aspects of nutrition (clinical), nutraceutical and pharmaceutical issues. The book will particularly focus on several intricate avenues including regulations around the world and regulatory hurdles, diverse nutritional challenges and potential health benefits, novel food innovation especially seed-to-clinic approaches, and future trends.

This book focuses on overview of food bioactives based molecules and the physiological roles performed by them related to disease prevention and/or treatment. Existing considerable overlap between food bioactives and drugs has been addressed in this book. The book presents the case for comparing and contrasting foods versus drugs in several models of health and disease, some of which are presented in further detail in subsequent chapters of this miniseries. Few chapters will review distinctive instances that will show the difficulty in-between metabolic processes influenced by foods versus drugs and that the two types of compounds exert overlapping or identical actions in prevention and treatment of disease.

To summarize we would say that the purpose of this book is to understand the adoption of food and nutrition/nutraceuticals in both prevention and treatment approaches to disease, and recommends that functional foods/nutraceuticals/phytomedicines can serve as efficacious adjuncts to pharmacotherapy during all stages of treatment of numerous diseases. This is a unique book it is first of its kind and fits in perfectly with today's health environment where demographically both young and elderly are addressed.









Interlink practices focus on following functions that are vital to our clients:

Functional Practices

Business strategy plans development & growth practice Marketing strategy & execution

practice

Categories, therapies & customer

insights practice

Brand management practice

Marketing practice (new product

development)
Sales practice

Profit & productivity improvement practice Business initiative practice

Capability improvement practice

Turn key projects

Business valuation practice

Industry Practice

Pharmaceuticals & Medical

Products

Functional foods / Fortified Foods, Medical

Foods & Nutraceuticals

Fine Chemical, Bulk drugs,

APIs & ANIs

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