InterlinkInsight

Perspective For Business Performance

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GAME CHANGING SHIFTS

Embrace Disruptions and Change Early!

Changing dynamics clearly signifies that of pharma industry is shifting its core to periphery. Core business is getting shifted from medicines to future medicines like biosimilars, biologics, etc. and this no longer remains in the domain of new chemical entities (NCEs).

Essentially it means those who can acquire small or similar size of non-core entities would add value to its operations. The acquired entities would be extended for same or similar target audiences. For this process, reliable Business Due Diligence becomes a corner stone to provide resources and balance the risk.

As there is a global watch on quality of Indian Pharmaceutical manufacturing irrespective of having robust processes and systems; it is now evident that we need to develop quality culture.
To encash on these trends we need to invest in R&D, new technology, quality culture, draw equity or debt to make us self-sufficient to expand and grow in international markets.

As prevention and treatment are becoming two sides of the same coin with changing paradigm from illness to wellness, essential aspects of regulatory cannot be forgotten. It's important to be updated.

After all why and for whom are we working? Where should be our focus? As industry, at the end we have to generate patient wellness and satisfaction.
In this edition of Interlink Insight I am sure you will get new ideas and thoughts that encourage you to connect different dots for the betterment of your business!

Looking forward to your reading and please let us know what you would like to read to shape up your business.
Have a great reading!

Dr. R. B. Smarta
Managing Director

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Pharma Game Changer–A Shift

"Market and industry structures are quite brittle, one small scratch and they disintegrate…" how aptly Professor Peter Drucker has captured today's situation of pharmaceutical industry. In existing range of new disruptive technologies, the pharmaceutical industry would reimagine its future. Overtime, the consciousness of preventing the illness and moving towards more targeted therapies, accurate patient diagnosis, using customized genetic mapping and use of technology will be trending in upcoming future.- By Dr. R. B. Smarta

Introduction:

Pharmaceutical industry has always been a highly profitable industry, and has historically been among the best performing industrial sectors in terms of return on investment. According to the International Institute for Management Development (IMD), India has moved one notch higher, to the 44th place in terms of competitiveness in the annual rankings.
Still industry is facing issues like stronger IP regulations and overloaded market. Similarly price controls from payers, margin pressures and patent expiries are also forcing companies to radically restructure in order to maintain their profitability.
As a result recent years have seen exciting breakthroughs in pharmaceutical industry that are producing truly novel therapeutics for unmet patient needs. Industry is in the transition state of preventing the illness, focusing on targeted new therapies, accurate diagnosis, expending on customized genetic mapping and advances in technology.

Indian pharma in numbers:

The Indian pharmaceutical industry is around 3.1 – 3.6% (in value terms) and 10% (in volume terms) of the global pharmaceutical industry. The industry is forecasted to reach USD 55 bn by 2020 and is expected to grow and achieve 100 bn by 2025.
India is home to around 3000 pharma companies with a strong network of 10,300 manufacturing facilities. Vaccines for over 50% of global demand in United States, and 80% of the antiretroviral drugs used globally to combat AIDS are supplied by Indian pharmaceuticals firms.

The biggest strength of the Indian pharmaceutical industry is the generic business. India is accounted for 20% of global generic drug exports. Almost 60,000 generic brands across 60 therapy areas and more than 500 APIs are manufactured in India.
The competitive edge of the Indian pharma over others is its cost efficiency and competency. The supporting factor for cost efficiency and competency in India is low production cost. Production cost is nearly 33 % lower as compared to US and almost half of that of Europe. This cost efficiency has created opportunities for Indian companies in emerging markets.

Shift in Industry:

1. Technological shift:
In existing range of new disruptive technologies, the pharmaceutical industry would reimagine its future. Consumerization of health enables patients to better understand and get more involved in managing their health. The effects of these changes and the speed, with which traditional ways of treatment are replacing, will definitely change the form of therapeutic area. Technology is trying to capture and make services affordable and accessible.

Bionics - biologically inspired engineering is the emerging field in healthcare sector. It will impact the way surgeries are accomplished. Well still in nutshell, scientists and doctors in India are still ambivalent about its application for betterment of society.
'Nanobot' an engineered nanorobot, at present a hypothetical technology, will be

designed at molecular level that can actually navigate independently through your blood stream and carry out functions like repairing of cells and prevention against infection. One of its applications is in field of hematology - Respirocytes are designed to function as artificial RBCs and are proposed to supply 200 times more respiratory gas molecules than natural RBCs of the same volume.

Some of the giant players like Amazon, Apple, Google and Uber are now focusing on healthcare segment. There is a huge space in India for technological growth. Hence the forward thinking mentality and giant technological players are now looking at India as an opportunistic fruit.

GenY will experience a world owned by technology and automation, whereby prescription based drugs can be ordered using Amazon prime, guidance will be provided by a nurse at the Apple Clinic, and an Uber ambulance will be at your door step on one click.

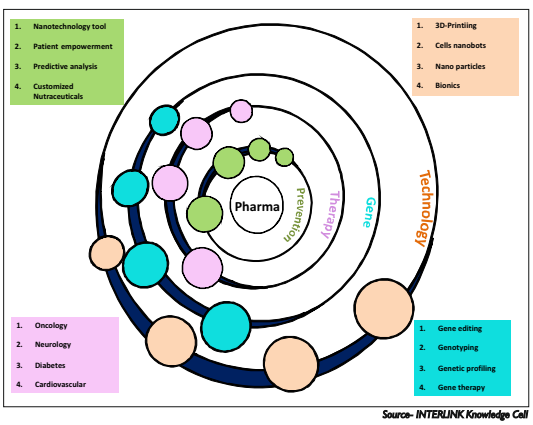

Figure 1: Pharma shift

2. Therapeutic shift:

Ground breaking new therapies will fill in the space of niche specialists. The Sales in the Indian pharmaceutical market was found to be 7.2 % on year to Rs 91.31 bn. in the month of December major share was supported by anti-diabetic and cardiac segment.

Diabetes segment: A per WHO report, India's 69.2 mn population is suffering from diabetes, from that 90% of the population is distressed from Type 2 diabetes. Some of the key factors leading to growth of anti-diabetic drugs are increasing awareness, increasing urbanization and health style pattern, increased spending on healthcare and healthcare insurance are leading to growth of the market. The market is anticipated to grow at the average CAGR of 6.5% in 5 years.

Cardiology segment: Cardiology segment last year generated revenue of Rs. 1115 cr. and is growing at rate of 8%. Amongst cardiovascular diseases, hypertension is the leading segment. Anti-arrhythmic drugs will probably lose its market share due to inclination towards implants such as pacemakers. Key factors driving the market are sedentary lifestyle, dietary habits, high blood pressure, high cholesterol, and smoking are foremost risk factors for heart disease.

Oncology segment: The aim while developing the medicines for cancer treatment has always been to cure the disease. But current treatments have no assurance of

cure, and subsequently, patients require extensive follow-up. India has around 1.8 mn people fighting with cancer. As per the statistics the common cancer faced by people are of breast, cervical and oral cancer. The ratio of doctors that are specially trained for oncology to that of cancer patients is about 1:200.
Neurology segment: It is estimated that about 30 mn. people in India suffer from various forms of neurological diseases and the average prevalence rate is as high as 2,394 patients per 1,00,000 of the population. Some of the major drivers leading to market growth are increasing prevalence of disease; increasing microwave radiations leading to neuronal damage, increase in disposable income, and rising awareness of healthcare.

3. Curative to Preventive shift:
The transition of the pharmaceuticals industry from its traditional business model is ongoing and interesting to see how their next blockbuster molecule could be derived through different routes. It is proposed that the industry is challenged with three interrelated tipping points referring to what the industry sells (service models vs. therapies), to whom (mass markets vs. niche), and how it should organize itself (making connections vs. integration). The transition from current 'high-risk, high-margin' pharmaceuticals business model to 'low cost high volume' nutraceuticals business model will be dependent on many factors.

The number of factors, such as increased lifestyle related diseases like diabetes, obesity, cardiovascular disease, mental illness, alzheimer's and parkinson's, changing work patterns, a surge in middle class consumer in developing markets will see nutraceuticals emerge as a growth area across the mature pharmaceuticals market. This prevention of disease trend has already manifested largely as self-care food supplements, functional foods and drinks, sports nutrition or 'superfoods' in the market niche of nutraceuticals. This trend is also bolstered by growing interest in personal nutrition which would be customized based on the needs of body as well as preferences for 'natural' and organic food products.

This will definitely lead for the dynamic growth of nutraceuticals which has seen more recently in emerging markets such as India, China and Brazil. Similarly these emerging markets will also help to offset the plateauing trend in US or Europe.

4. Genetic shift:
Currently the scientist are interested in applying pharmacogenetics and are focusing upon the genetic basis of drug response from the perception of congenital traits and ethnic differences. Well the differences in drug response are due to dissimilar drug metabolism. Genetic probe testing, genotyping is soon going to hit the market with automization.

Theoretically, it can be applied in an outpatient setting to the manner similar to glucose and blood testing at present. With increasing use of artificial intelligence the patient information may be profiled on the data house server and the pharmacist, doctors, can readily interpret the patient's response to certain drugs and accordingly decide the treatment.
Applications of gene therapy are validated on the basis of clinical trials, selected cases, and studies based on animals and humans. Few diseases that can be treated

using gene therapy are as mentioned, Adenosine deaminase (ADA) deficiency, Familial hypercholesterolemia, Acquired Immune Deficiency Syndrome (AIDS), Hemophilia B, Cystic fibrosis, Cancer.

Value addition by means of R&D:

As we know that the first switch to alter the business model is nothing but R&D. According to the Economic Survey the country's spending on R&D, in terms of GDP, has been stagnant at 0.6 to 0.7 % Since last two decades and was found to be much inferior compared to US, China, South Korea and Israel. So to bring India to the next level in global pharmaceutical industry the national expenditure on R&D has to be increased. The regulatory body DCGI (Drug Controller General of India) has also advised the local pharma companies to look at R&D and develop innovative products.

Even all pharma leaders know that the successful method to guarantee future success is to bring promising pipeline to market. The Reliance Mutual Fund, deputy CIO, Sailesh Bhan, recently mentioned that huge pharma giants like Sun pharma, Lupin, Dr. Reddy's lab are investing Rs 2000 cr. each on research and predicts well for their growth forecasts towards building product pipeline and ventures into niche areas in the US.

Although the pharma industry is progressing in R&D, the principal weakness lies in regulatory price capping that limited the research and development because of cost factor. So to overcome this, the government is also organizing for a multi-billion dollar investment with 50% public spending. This enables companies in India for 100% foreign direct investment from investors. This affirmative signs are surely going to encourage and support the future of pharmaceutical R&D.
What might 2025 look like?

Looking at the disruptions that the industry faced, to withstand a strong growth rate by 2020, companies will have to realign their business plans and strategies. The companies need to take efforts to develop core strength and improve operational efficiency and productivity. Investing and developing the business plans taking into account the growth of segments like health insurance, medical technology and mobile telephony can help the company to engage patients and customers, as this new trends are the key growth initiatives.

Think it through:

As the shift in market is non-reversible, think across to upgrade quickly to one of the tendency and realign existing pharma business towards new shifts swiftly. More time the company takes; more will be loss of time and revenue with progressive depleting profits.

Is it not worth to think and prepare for future to work on strategic shift with augmented core strength?

About the Author

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Special Feature

In Pursuit Of Betterment- M&A

Since years, the Indian economy has stayed robust owing to unwavering macroeconomic environment, eased credit conditions and the continued progress on policy reforms. Though the demonetization has shaken up the businesses and small organizations are still trying to come over it, the wave of corporate marriages- "Mergers & Acquisition" is trending, and what needs to be examined is the degree to which they have succeeded. – By Mr. Bharat Parwani

Introduction:

In past years, we have seen a spurt in Mergers & Acquisition (M&A) activity in the Indian Pharma Market from both MNCs as well as Indian companies. While there has been an increase in M&A activity, research has shown that all M& A transactions don't succeed in achieving the objectives which were set out while entering into a transaction. One of the most critical factors in ensuring the success of M&A deal is to do a proper, comprehensive Business due diligence and Value creation before signing the definitive agreements.

"Transactions 2017" an E&Y paper stated that Indian pharmaceutical sector witnessed 51 pharma deals in the year 2016, with a total deal value of US$ 4.6 bn and maintained its prominent position in the global generic pharma market, due to major advantages like large number of USFDA approved sites coupled with low Capex and operating costs. However, as per Grant Thornton Advisory Pvt. Ltd, there have been around 27 M&A deals in third quarter of 2017 in pharma and healthcare which valued at US$ 719 mn. This seems to be way below 54 deals,valued at US$ 4.7 billion in 2016.

Evaluating M&A:

M&A must be justified by the creation of value for shareholders, by achieving cost savings and synergies. In financial terms, the value of synergy is defined as the incremental value created by business units working together as part of a firm, compared to the value creation by the units operating independently.

Synergy may be created by:

1. Capitalizing on core competencies, such as R&D expertise and marketing skills.
2. Sharing common infrastructures, such as production facilities, marketing channels, and procurement processes.
3. Increasing market power by creating a stronger bargaining position between customer and suppliers.

To recap, some of the recent M&A deals involving the Indian pharma companies are summarised below:

Major M&A deals in India:

Merger between Ranbaxy and Sun Pharma- The merger of Ranbaxy and Sun Pharma led to the emergence of one of the biggest pharma companies in India. The deal valued at US$4 bn. was completed in March 2015. The transaction lead Sun Pharma to acquire fifth position globally in pharmaceutical sector in terms of revenues, with operations in over 55 markets and 40 manufacturing facilities globally.

Dr Reddy's Laboratories acquisition of select UCB India portfolio- In 2016, Dr Reddy's Laboratories acquired a select portfolio of Belgium-based pharma company UCB in India for Rs. 800 cr. ($128.38 mn.) on a slump sale basis. The acquisition was part of Dr Reddy's Lab strategy of strengthening its domestic portfolio (additional sales of about Rs. 150 cr business.

Cipla's acquisition of two US-based pharma companies- In 2016, Cipla, acquired two US-based generic companies InvaGen and Exelan, worth $550 mn. in an all cash transaction. The development marked an important step for Cipla in expanding its foothold in one of the biggest pharma markets in the word.
Lupin's acquisition of US-based Gavin- In July 2015, Lupin completed its outbound acquisition of the New Jersey-based privately held generic drugs company GAVIS Pharmaceuticals LLC and Novel Laboratories Inc. (Gavis) for $880 mn.
Acquisition of Piramal Healthcare by Abbott- US-based Abbott Laboratories acquired the domestic formulations business of Piramal Heath care at a consideration of $3.72 bn. (Rs 17,500 cr.) in May, 2010. The acquisition was key to enter into new emerging markets in the pharma sector and expand its patented product business.

Daiichi's Acquisition of Ranbaxy- In June 2008, Daiichi Sankyo, Japan's third-largest pharmaceutical company acquired a controlling stake in Ranbaxy Laboratories, India's biggest generic drugs maker, in a cash deal of approximately $4.6 bn. It was one of the biggest acquisitions of an Indian public company.

Justifier- Business due diligence:

In simple terms, business due diligence is a process through which a potential acquirer evaluates all aspects of the target company or its assets for an acquisition before entering into an agreement or a financial transaction with the target company. It is important that Business due diligence covers not only financial implications (impact on top line sales, value creation, P & L etc.) but also other aspects (e.g. organisation culture).

Before acquiring a company or its assets, acquirer should have a very good idea of following:

- How has the target company performed over the last few years? Have they been growing in line OR faster than the market? What are the reasons for the same? If they have been growing faster than the market, are these reasons sustainable.

- What is the expected growth of the business in the future? Which segments are they participating and what is the future growth prognosis for those segments?

- Who are the major competitors? What are their business plans? Any new technological breakthroughs expected which may impact target Company's future growth?

- What are the major risks involved? Any issues foreseen during the process of acquisition and subsequent integration?

All these questions support the Business due diligence.

As we can see from above, the Business due diligence and value creation analysis helps the Buyer to evaluate the predictability and the attractiveness of the business to be acquired as well as the potential risks, all of which is essential to the potential Buyer before signing the definitive agreements.

Summing up:

The pharma segment is experiencing a radical shift as elaborated in On the Cover article, and the main drivers that are driving M&A are extreme price pressure in the US, declining niche product pipeline, patent expiry of various blockbuster drugs. Whereas, the domestic companies are intend to expand and invest in overseas market. This is likely to embrace different type of product-mix, including specialty products, biosimilars, use of IT enabled technologies to track and monitor the distribution, customised healthcare products.
Going forward, the critical drivers for pharma M&A in India, both inbound and outbound, are unlikely to undergo any radical change. Interestingly, available research studies regarding its long-term impact on the companies involved in this process are not yet conclusive.

To sum up, M&A is an exciting activity in these times when companies are struggling for top line growth in pharma. The trend is likely to continue and even accelerate going forward. Well it is found that the financial impact of M&A's on the merged entities in India last no more than short to medium term. However, comprehensive Business due diligence and value creation analysis is critical to increase the probability and may fail, but it is in pursuit of betterment.

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Medical Consumer Guidance- Claims

Every day consumers encounter wide range of dietary supplements and nutraceutical claims to improve health, manage the conditions and reduce the disease risk. So the demand for nutraceuticals is increasing but in terms of claims it still resides in the grey area between pharmaceuticals and food. - By Ms. Shruti Patil

Introduction:

Though specific regulatory framework exists in different countries, nutraceuticals are experiencing challenges with safety and health claims and their substantiation. Also there is a big spurt in the number of products with exaggerated health claims. So, to achieve a high degree of consumer protection, to ensure confidence in nutraceuticals products, to promote fair trade, to stimulate academic research and to encourage product innovations clear claims has become necessity for the industry.

Evidence based nutrition health claims:

Nutraceuticals could be effectively used to prevent and cure some illnesses. But for that safety and efficacy evidences are needed. The global regulatory environments have invariably set requirements for scientific substantiation of claims. And human intervention trials placed at the top of a pre-defined hierarchy of evidence. Similarly, the recommendations by Codex are globally authorized and are intended to assist national authorities in their evaluation of health claims in order to determine their acceptability.

A "health claim" by definition has two essential components: (1) A substance (whether a food, food component, or dietary ingredient) and (2) A disease or health-related condition. A statement lacking either one of these components does not meet the regulatory definition of a health claim. For example, the statement which addresses a role of dietary benefit or a statement which claims to maintain a good health in general is considered to be dietary guidance rather than the health claim. (Source: USFDA)

The type and extent of the evidence required will be determined by whether the claim relates to a particular diet, a food category, a specific food, a proprietary (product-specific) product or a food constituent.
Usually there is a comparison between drugs and nutraceuticals clauses; although, it is clear from FDA that all claims related to mitigation of clinical conditions is part of drug claims and not of nutraceutical claims.

Difference in drugs and nutraceuticals substantiation of claims:

Drugs are intended for, and evaluated in, sick people. Food and food constituents with health claims are aimed at the normal healthy population. Drugs typically have only one, or a few, principal endpoint or outcome measures, where the effect of a drug is usually measurable and drug trials are typically evaluated relative to the absence of drug. In most cases, drugs act quickly and their endpoints can be measured over relatively shorter periods of time.

Few of these features fit the nutrition context. Nutrients and other substances that contribute to nutritional or beneficial physiological effects tend to manifest themselves in small differences over longer periods of time. Nutrients work together rather than in isolation, and often their effects will not develop when intakes of other dietary components are suboptimal. There is, in effect, rarely a nutrient-free state against which the nutrient effects can be compared. Typically,

studies compare a low intake with a high intake, but responses will be influenced by threshold characteristics, e.g. calcium absorptive response to vitamin D or hemoglobin response to iron.

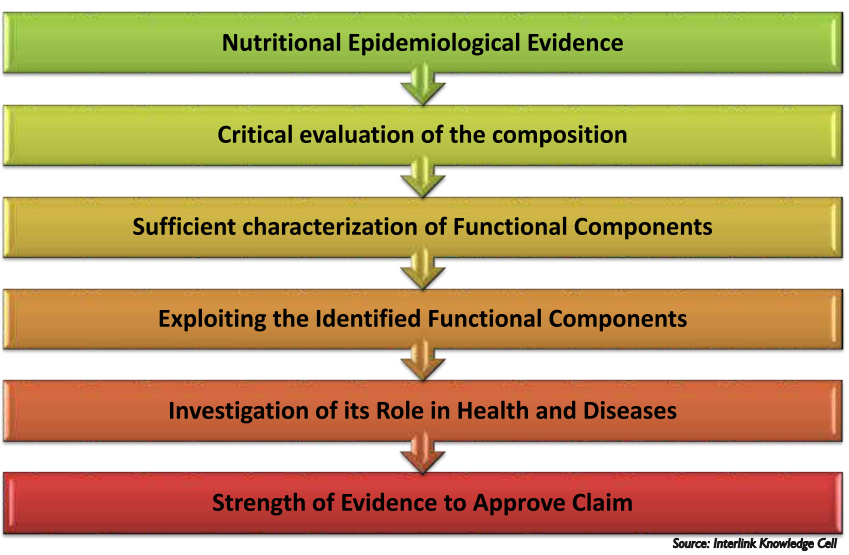
Following table gives an overview of difference in the parameters needed for substantiation of "evidence based" claims.

Sr. No.	Parameter	Drugs	Nutrients
1	Those human subjects with disease at baseline	100%	0%
2	Essentiality	None	Essential
3	Homeostatically controlled by the body	No	Yes
4	True placebo group	Yes	No
5	Dose-response	Relatively easy	Difficult in context of varied, balanced diet and healthy lifestyle
6	Biomarkers	Validated biomarkers of disease (few)	Research needed to identify adaptive responses in healthy individuals
7	Targets	Single organ/tissue	All cells/tissues
8	Systematic function	Isolated	Complex network
9	Baseline 'status' effects response to intervention	No	Yes
10	Effect size	Large	Small
11	Side effects	Large	Small
12	Nature of effect	Therapeutic	Contribution to, and/or role in growth development or functions of the body; maintenance/improvement of health reduction of risk of disease

Source: IADSA

Table 1: Parameters Needed for Substantiation of Health Claims

The dilemma of focusing on pharmaceutical approaches to evidence-based nutraceuticals and the reliance on Randomized Control Trials (RCTs) to assess nutrition questions fail to address the limitations of this pharmaceutical approach to nutrition.



Source: Interlink Knowledge Cell

Fig. 1: Parameters Needed for Substantiation of Health Claims

Scientific framework for substantiation of nutraceuticals health claims:
The proper starting point for substantiation of health claims for Nutraceuticals should begin with the identification of an appropriate epidemiological target. Once the epidemiological evidences are created then the next step is of critical evaluation of the composition. This step is followed by the characterization of the product with the functional components and exploitation of the identified functional components. After that the investigation of the ingredient is carried out to determine its role in particular health and diseases. The last step of the protocol is the validation of pre-intervention data with the help of human intervention study.

Health claims should primarily be based on evidence provided by well-designed human intervention studies. Human observational studies, animal model studies, ex vivo or in vitro data may be used as a supporting knowledge for the relation between food or food constituent and their health effects but cannot be considered to substantiate any type of health claim.

Methodology:

The methodological quality of each type of human intervention study should be assessed for its study design and statistical analysis. The design of this study should include the following considerations:

a) To study and select groups of candidates which are representative of the target group.
b) To create appropriate controls with an optimum duration of exposure and to follow up to demonstrate the intended effect.
c) To carry out characterization of the study groups' background diet and other relevant aspects of lifestyle along with an amount of the nutraceutical component with its intended pattern of consumption.
d) To study the effect of the nutraceutical component and dietary context on the functional effect of the component.
e) To monitor the compliance with intake of nutraceutical component under test.
f) To conduct the statistical analysis of the data with methods recognized as appropriate for such studies by the scientific community and with proper interpretation of statistical significance.

When there is a difficulty in measuring the true endpoint for a claimed benefit, studies should use the markers and biomarkers. These markers should have a known relationship with the final outcome as well as they should be methodologically valid in terms of their analytical characteristics. Finally the claim should be substantiated by considering the totality of available data and by weighing of the evidences we create in pre and post human intervention studies.
It should be noted that the study without the relevant scientific data & appropriate statistical measurements and with major design flaws cannot be applicable to the targeted population for a health claim.

It should be taken into consideration that the necessary time to develop a new nutraceutical product is reduced compared to time required to develop a new

drug, considering the natural origin of the constituents of a nutraceutical and that a nutraceutical is formed by many natural substances (not by a single substance, as in a drug).

Three types of claims:
FBOs are allowed making 'Nutritional' or 'Health' claims provided there is direct or implied relationship between the nutrients or ingredients used and there is a documented scientific basis. Depending on this, claims can be made on the basis of nutrients and health benefits.

Nutrient Claims:
- Nutrient content claim: A nutrition claim that describes the level of a nutrient contained in the food (e.g. 'source of calcium', 'high in fiber' and 'low in fat').

- Comparative claim: A claim that compares the nutrient levels and/or energy value of two or more foods (e.g. 'reduced', 'less than', 'fewer', increased', 'more than', 'lite/light').

Structure / function Claim:
This claim implies the role of a nutrient or dietary ingredient intended to affect a structure or function in humans. Similarly, such claim defines the means through which dietary ingredient may act in the human body to maintain general wellbeing. (e. g. calcium builds strong bones)
Health Claims:
The health claims can be divided into three categories:
- Reduction of disease risk claim: It states that product, along with the total diet, reduces the risk of developing a disease or health-related condition. (eg. plant sterol have shown to reduce cholesterol levels which is a risk factor in the development of coronary heart disease)

- Health maintenance claim: This claim states that the product promotes health by reducing the risk of serious illness. (eg. helps improve your mood)

- Enhanced Function claim: The claim which offers a specific beneficial effects on a nutritional or physiological function on the consumption of ingredient. It also provides information of their positive contribution through improving or preserving health. (eg. calcium for healthy bones and teeth)

Along with the above claims there are two more claims namely; anti-ageing claim and immunity claim which are added by FSSAI through which nutraceutical industry is trying to capture the evolving consumers.

Recent FSSAI amendments for health claims:
In India, the Food Safety and Standards Authority of India (FSSAI) has issued directions regarding the claims to be mentioned on the products. Such regulatory supervisions are critical in India considering the fact that there were many incidents of improper claiming of conditions by these products.

However, the FSSAI Act has made two amendments in the span of two years from 2016-2018. As per these amendments, FSSAI has clubbed Food for Health or

Dietary Supplements, Food for Special Dietary Uses, Food for Special Medical Purposes under the same definition of nutraceuticals. All such products now have to comply with the general requirements as well as specific labelling and claim conditions as specified under the category of nutraceuticals.

The regulations which have been made operational from December 2016 include standards for wheat flour, rice, edible oil, milk and salt which can be fortified with micro-nutrients like vitamins A and D, iron, folic acid, vitamin B12, zinc, thiamine, riboflavin, niacin and pyridoxine. As per this amendment now the product fortified with vitamin A should be claimed as "Helps against night blindness".

The recent amendment which has issued its long awaited rules for functional foods and supplements has reinforced from 1st January, 2018. As per this amendment one of the key rules now nutraceutical companies should follow while claiming health supplements are "Not for Medicinal Use" with the claim of "health Supplements".

Way forward:

It is necessary to have transparent consumer guidance claims framework for regulators to judge and make decisions about the acceptability of a health claim submitted by an applicant. Similarly, developed scientific framework can help to identify gaps in research by weighing the totality of the available data and by scientifically validating the relationship which is demonstrated.

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About the Author:

Ms. Shruti Patil is a Senior Research associate in Interlink Consultancy and has worked on projects and more than a dozen Nutraceutical articles published in reputed magazines and also on digital media. Being Masters in Nutraceuticals and having an insight of different Nutraceutical ingredients, their usage in different dietary as well as nutritional sufficiency and hands on experience on Nutraceutical and business project, she would like to pursue her career in Nutraceuticals based on biologics, nutraceuticals and development of this industry as business.

Nutriscope

"The aim of marketing is to know and understand the customer so well that the product or service fits him and sells itself." As per Professor Drucker's insight, being updated with the present market is the key to create a future! The world of dietary supplements is no stranger to change. This insight can very well hold true looking at the current scenario of the market. We also see a growing awareness among consumers about healthy living and wellness, which seems to be one of the major drivers of the dietary supplement industry. – By Interlink Knowledge cell

Introduction:

The increasing awareness, increase in lifestyle diseases have led to the development of a promising dietary supplement market involving products to prevent diseases or providing health benefits related to lifestyle issues. With the rising incidence of metabolic disorders in India, people have realized that nutritional correction can play a major role in improving the quality of life and preventing or tackling a variety of diseases.

Thus, adoption of dietary supplements as a preventive healthcare to avoid rising cost of medical treatments will drive India dietary supplements market in the coming years.

Market Growth:

When the global dietary supplement market is about to cover 38% of the nutraceutical market, India is no behind in the competition. 2017 has seen lot of trends emerging in the Indian dietary supplement industry and 2018 is considered to uplift the market further.

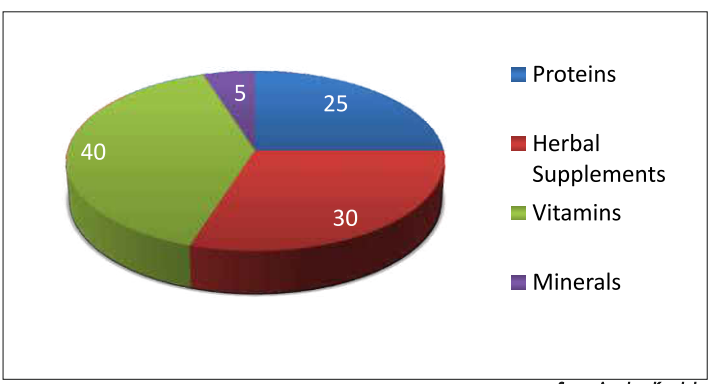
The Indian nutraceuticals market has grown from 2 bn. to 4 bn. over the period of last ten years and is expected to cross 10 bn. by 2022. In these dietary supplements is the largest category accounting for 62.5%, driven primarily by the pharmaceutical sector in the form of vitamin and mineral supplements. The Indian dietary supplement market has reached 2.5 bn. USD in 2017 and expected to touch 5.90 bn. USD by 2022 at CAGR 19%.

Seven Current Trends:

There are seven major trends that will drive dietary supplement industry in next few years.

1. Trend in Segmentation:

The market for dietary supplements in India is broadly classified into vitamins and mineral supplements, herbal supplements, protein supplements and chyawanaprash variants.



Source: Assocham Knowledge

Figure 1: Indian dietary supplement market share -segment

- Vitamins and minerals dominated the market with revenue share of 40% in 2017. The intake of vitamins and minerals supplements has increased over the years due to the high prevalence vitamin deficiency.

- Probiotics supplements market grew at CAGR of 19.80% during 2014-19 and has recorded as the fastest growing segment in the dietary supplement market of India. High consumption of tobacco, westernized food and spices coupled with malnutrition has resulted in large prevalence of digestive diseases in India. For management of such disorders, doctors are suggesting more use of probiotics.

- Dietary supplements also contain herbs plant or parts of a plant are called herbal supplements which covers around 30% share of the market. For example, Aloe has been marketed as a remedy for coughs, cold, etc.

- Protein supplement is expected to show significant growth over the forecast period. Increasing innovation in the manufacturing of proteins targeting specified functions including energy balance, weight loss, muscles repair is expected to promote the industry expansion. Currently, the protein contains 25% share of total supplement market.

- Omega-3 dominated the remaining 5 % of market. Omega-3 fatty acids have been used in food fortification and dietary supplements for a long period in India. It is estimated that the omega -3 supplement market will grow by a healthy rate of 11.4% CAGR from 2013 through 2020.

2. Demographics dynamics:

The dietary supplement market in India is penetrated 10% at all India level. The penetration rate is high in urban India at 22.51%, where as in rural India it is merely 6.32%.

Cities in India such as, Delhi, Mumbai, etc., have witnessed industrial growth at a much faster pace, hence these cities have also witnessed significant rise in lifestyle diseases such as, blood pressure, over-weight, etc., thereby increasing demand for dietary supplements.

3. Lifestyle of a consumer:

Consumers' modern-day lifestyle has significantly changed in the last three decades. Faster pace of life, stress of work, has been taking its toll on health and wellness. At the same time, most of the households have a double income.

The suppliers' growing efforts on building brand identity and value have created wider awareness. Retail products fortified with nutrients such as omega-3 fatty acids and vitamins are now being considered essential parts of consumables.

Access to media and information has allowed the consumers to better understand the latest developments in this space. Generally the current generation is extremely conscious of dietary supplements as rituals like work-outs, swimming, running etc. need a supplement that caters to nutrition needs well.

4. Marketing:

New trends in value chain- distribution channel also has a major role of building and sustaining consumer, brand building and accelerating reach of such products. Sometimes it is sold as an OTC, so chemists' shops would be a familiar channel for the purchase. Chains like Neulife are inspiring, perhaps setting benchmarks for other entrepreneurs to venture in such distribution initiatives. Exclusive outlets provide more credibility to consumers as also it builds up a relationship with the buyers.

Like many others, the dietary supplement industry has been subject to a major shift in consumer purchasing preferences. The move away from traditional "brick and mortar" stores to e-commerce is growing exponentially. According to TABS Analytics' 2016 an impressive 78% of all online shares for the dietary supplement marketplace are currently being held by retailers with business models that do not include a brick and mortar presence.

Similarly, competitive value propositions with respect to unique offerings have resulted in expanded product offerings. This aids in providing consumers with more options to choose to fulfill their requirement.

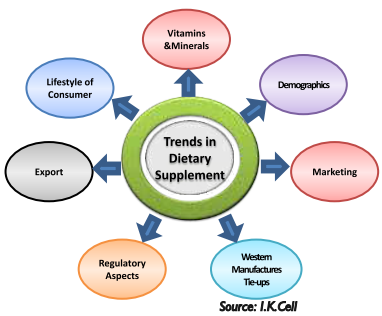


Figure 2: Trends in dietary supplement

5. Western manufacturers' tie-ups:

A trend is emerging, where western nutraceutical manufacturers and distributors are eyeing Indian nutraceutical or dietary supplement companies. They are on the lookout for tying up with Indian companies with innovative products. Their point is India with its rich 5,000-year history of traditional medicines from systems such as Ayurveda, Siddha and Unani, has got an advantage over others to evolve a new medicine from the existing knowledge.

Many multinationals like Monsanto, American Home Products, DuPont, BioCorrex, Abbott Laboratories, Warner-Lambert, etc. are interested to invest in India because of the untapped market.

6. Regulatory aspects:

India is one of the countries, where the dietary supplements are sold under the name of Fast Moving Healthcare Goods (FMHG). To serve as a single reference point in relation to regulation of dietary supplements, on Dec. 23, 2016, the first legislation regarding health supplements and nutraceuticals in India

has been finalized. FSSAI notified the finalization of "Food Safety and Standards Regulation, 2016", which has been formally implemented from Jan. 1, 2018.
This new regulation covers the provisions for eight food categories including health supplements, and specialty food containing plant or botanicals, food containing probiotics. As this is the first legislation regarding dietary supplements and nutraceuticals in India, it will have a significant impact on the domestic market as well as overseas exporters aiming to enter the health supplement and nutraceutical market in India.

7. Exports:
With increase in demand and conductive regulatory structure in place for manufacturing units, the export market can thrive benefiting the growth of the dietary supplement industry in addition to the already achieved 2.5 bn USD, giving a hope to the industry to march towards 6 billion USD. India possesses advantages such as cost effective manufacturing, availability of talented and inexpensive human resources, and is a hub to a large number of medicinal plants, trees and herbs (bio assets).

Concerns:

The main two concerns of dietary supplement market are the apprehension of side-effects that it may cause and the reservation that these products are not 'natural'. Marketers need to take such points of views in consideration and launch sustained communication programs of outreach that will allay such fears both in the minds of opinion leaders as well as consumers.

As the dietary supplement market will mature in India, in coming years shelves will be full of dietary supplement products giving opportunity to consumers to select from many alternatives. But the concern in such situation is invasion of foreign competitors. They will not only go after high end market in India, but will target the middle and eventually the low end market.

In this case the main defense for Indian companies will be developing stronger skills in innovation, differentiation, branding and service, in another word, marketing! There are certain questions that manufacturers can ask them to succeed in their business:

Can we meaningfully forecast?

India dietary supplement market is expecting the growth at a CAGR of 19% during the five years forecast period from 2016-2022.

The Dietary supplements targeted at women and children have a bright future. Preventive dietary supplements for diseases such as cancer, diabetes, obesity and arthritis are also much sought after. Deficiency of vitamin D will act as driving factor with approximately 65% of the population being deficient of vitamin D.
However, the growth is expected to decline between 2019 and 2021 owing to the fact that market would be flooded with nutraceuticals by this period, and the companies would compete on the basis of price.

What is ahead!

If dietary supplement industry has to showcase beyond 2.5 bn USD, there is no choice but to leverage on all current trends for every company and decide on…

Hobbson's choice!

1. Where to play? Which disease areas have dietary factors that contribute to disease risk and progression, and which of these are underserved by current medical approaches?

2. What is the business model? Who are the stakeholders who are likely to drive adoption and use of the dietary supplement (consumers, physicians, others)? What channel is best able to activate that adoption?

3. How to promote? How can you drive adoption by developing scientific evidence, leveraging communication ecosystems (patient message boards, social media, etc.), and aligning financial incentives?

4. How to improve capability? How do you acquire the capabilities to succeed?

5.How to maintain Quality & Claims?

Let's work towards 6 bn USD. It is possible!

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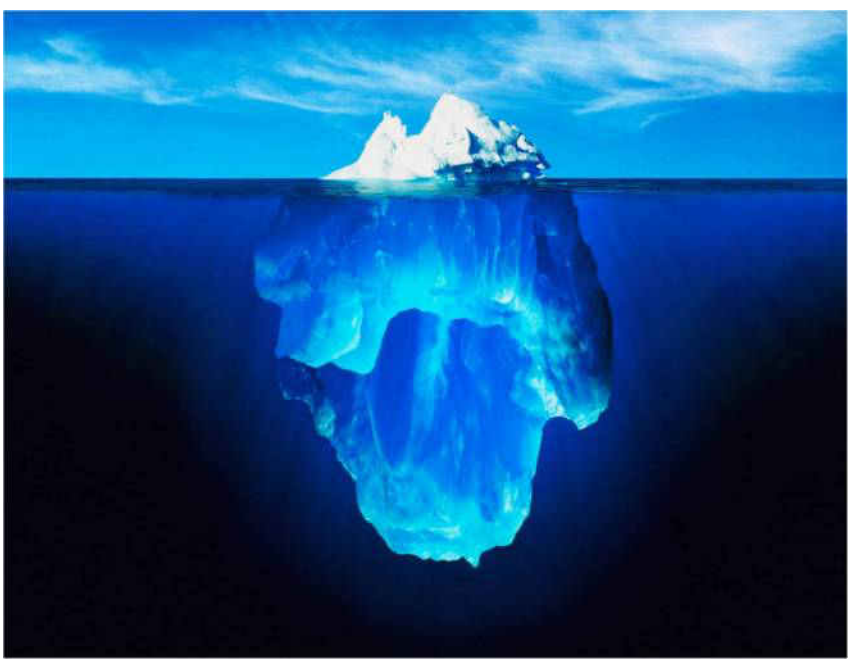
About the author:

Interlink Knowledge cell

Building New Quality Society



The pharmaceutical industry in India has been experiencing consistent growth. Nonetheless, it also faces many unique challenges. These include all of the difficulties inherent in exporting to the US market, the challenge of meeting the complex quality standards of the FDA and the growing competition from China and other Asian countries, especially in the area of API's. The article explains how can quality culture - the next stage in quality evolution - help us to achieve these goals? - By Interlink Knowledge Cell.

Introduction:

All of the companies in the pharmaceutical industry in India, like their competitors around the world, seek to achieve the following goals: reducing the cost of poor quality, which is estimated in the US to cost companies 65 mn $ for every 5000 employees keeping high standards of safety in the product manufacturing process. Developing and maintaining both employee and customer satisfaction, strengthening the company's reputation regarding the quality of their products and reducing the number of customer complaints is also crucial.

India's pharmaceutical companies are looking more than ever for ways to meet these complex challenges, especially considering the severe level of competition in both the local as well as global markets.

Employees and managers bring their cultural background to the workplace:

During many workshops, seminars and trainings that we have facilitated throughout the world on the topic of creating a quality culture, we asked groups of mid-level and senior managers to describe how they view the three values of personal responsibility, ownership and accountability, which are the three essential building blocks in creating a quality culture.

In order to do this, we asked them to step outside of their workplace roles for a moment and describe how they perceive these values in their lives at home. I felt this was very essential, as all values begin in the home. You might be surprised to learn that these managers knew exactly how to describe the three values of personal responsibility, ownership and accountability as they were expressed in their homes and pertaining to their families. From adopting measures to ensure the safety of their family - without compromise, and without transferring the responsibility to anyone else - to educate their children and instilling in them the value of respecting their parents and other adults.

This was the culture in which they were raised and educated, and this was how they raised and educated their offspring. In this manner, the values of their culture endured and were passed down from generation to generation.

However, when we transitioned to a discussion regarding **personal responsibility, ownership** and **accountability** in the workplace, as it related to events such as dealing with errors and deviations, or taking full responsibility for one's actions, most of them placed the responsibility for errors and deviations upon their supervisors, subordinates and colleagues.

They preferred to speak about collective responsibility, rather than individual and personal responsibility. We questioned them regarding this contradiction. Why were they dealing with important values one way at home, and another way in their workplace? As one of the senior managers expressed it to us, why would they be diligent and careful in their homes, but not equally as diligent and careful in their workplace, for example when it came to reporting deviations and errors in a transparent and timely manner? Why were they not able to assume personal

responsibility for their errors and learn from them? Why were they able to easily understand the importance of cooperation and teamwork at home, but not the importance of efficient collaboration and teamwork in their workplace - particularly between the quality and operations teams?

It became clear to us that there existed a blind-spot in their ability to see the critical importance in the workplace of the same values that they were able to envision so easily when it came to their lives at home. It is precisely for this reason that the creation of a quality culture in the workplace is so essential, in order to ensure an effective, efficient and safe work environment, one that enables people to align and implement their inner values and quality-related behaviors in their lives at work, in the same way that they implement these values in their lives at home.

The effectiveness of existing quality-management systems:

Do existing quality management and training systems provide an effective and comprehensive solution to the challenge of creating and maintaining a high level of workplace quality? According to research, this seems to be a part of the problem. For example, the Six Sigma training system failed to produce the desired results 60% of the time. The same was true for the Just-In-Time training system. A survey also found that only 20% of companies with LEAN quality management systems reached their anticipated targets.

Challenges of transformation:

What are the challenges for both managers and employees in creating an environment in which leaders are not only managing quality systems, but also establishing and managing a quality culture? How to transform the management and workforce for maintaining quality culture?
What are some of the critical indications that it is time to think about a quality culture transformation?

When you realize that the actual quality systems are not sufficient to achieve your performance goals.

- When you realize that the actual quality systems are not sufficient to achieve your performance goals.
- When senior site management is not putting quality at the top of their agenda: not communicating it, not discussing it, not emphasizing quality, and are even resistant to quality-focused initiatives.
- When quality requirements are underestimated in comparison to the emphasis placed upon operational demands.
- When a quality vision and quality values have not been created as a part of the organizational strategy, are not embedded in all HR activities (recruitment, training, ongoing evaluation), and operational processes and quality goals are not part of the company's performance metrics.

- When there is a lack of formal mechanisms for collecting and analyzing customer feedback and satisfaction levels.

Why is implementing a quality culture today more important than ever?

First and foremost, because we continue to pay a high price for poor levels of quality, which directly harms our profitability. A lack of quality culture results in problems with regulatory agencies such as the FDA in the United States. Companies with a highly developed quality culture spend 350 mn US $ less on average fixing mistakes than a company with a poorly developed quality culture. However, the benefits of a quality culture are not only related to a company's bottom line.

Quality culture is a comprehensive system that positively impacts all of the important stakeholders within the company; top-level executives are better able to implement their company-wide vision and strategy, senior and mid-level managers are more engaged and effective and employees are more committed to achieving quality processes and goals, and utilizing quality oversight and maintenance systems.

Leading pharmaceutical companies apply the concept of a quality culture not as a substitute for their existing quality management systems and processes, but as a strong foundation upon which those systems are built. A quality culture is critical to research and innovation within the company, and the development of new and effective products.

A quality culture raises the level of employee satisfaction, increases employee engagement and decreases absenteeism as well as decreasing employee turnover. Quality culture also makes a huge difference with customers and patients.
It preserves the highest level of product quality and safety, and raises rates of customer satisfaction and loyalty. It helps a company to better meet regulatory standards. It allows a company to meet its business targets, strengthen its competitive advantage and strengthens a company's brand and reputation in the global marketplace.

Implementation of Quality culture programs (QCPs):

We implement quality culture through several channels, both rational and emotional. to achieve this goal, we first work to raise awareness of the importance of quality culture, because this awareness will create in people's minds a new reality that can then be transformed into new actions.
Through this process, employees become aware of the relationship between their actions and various outcomes and their consequences. In parallel, we create a supportive work environment that helps to change the employee's point of view regarding the important topics mentioned previously: assuming personal responsibility, admitting mistakes, etc.

We also emphasize factors that empower the employee, such as giving and receiving feedback, employee recognition and establishing a culture of fearlessness. All of these factors help to create a positive environment for the new quality

culture.

Establishing a quality culture environment requires senior managers and direct managers to re-define their roles as coaches and motivational leaders of their team. Many of the companies that we have studied in the past have lacked these factors in their leaders, or misunderstood how to fill these roles properly in order to empower and motivate their employees.

We believe a quality culture can best be expressed through specific and concrete behaviors. Therefore, we focus on defining the key quality behavior success factors and implementing them through two-way communication, both from the top down and from the bottom up.

Phases in developing Quality culture and outcomes:

Phase One:
Mapping the quality culture and quality-related behaviors and establishing those behaviors within the organizational infrastructure.
The main outcomes of this phase are: A) The creation of a working plan which consists of a strategic path for goal implementation. B) Articulating the quality vision and mission of the QCP based on your organization's quality values. C) Establishing procedures and processes for implementing the internal QCP. D) Creating practices, success metrics, quality controls, monitoring methods and procedures for the program. E) Establishing the local champions forum which is responsible for executing the project at each site.

Phase Two:
Training the managers and local champions to execute their roles and implement the QCP methodology and the quality related behaviors.
The main outcomes will be: A) A Quality culture infrastructure for the implementation of the QCP. B) Champions and managers who are trained and prepared to execute the QCP methodology. C) Employees who are aware of the importance of the quality of their work to the patient and to the critical quality-related behaviors.

Phase Three:
Preparation for the quality culture launch week and the implementation of the QCP processes.
The main outcomes will be: A) An improved supportive work environment in order to create the quality culture transformation. B) A higher standard of leadership and a commitment to quality procedures and quality culture. C) The training and motivation of employees who are involved and committed to the quality improvement processes.

Phase Four:
Measurement of the Quality Culture Program implementation.
What we measure: A) Employees' motivation to accept the quality culture transformation. B) Employees' engagement in reaching quality goals. C) Employees' understanding and engagement with the quality values and the quality-related behaviors. D) The impact of the QCP on the implementation of the quality-related

behavioral changes.

The results

The results of the implementation of the QCP are quite impressive. The QCP contributes to raising the bar of product safety. The QCPs raise the level of employee satisfaction. It helps to better meet regulatory standards and business targets. It establishes a culture of personal responsibility, ownership and accountability - all fundamental factors in the creation of a quality culture. In various surveys, managers and employees reported that after the QCPs implementation they gave more of a priority to quality.

There is a greater understanding by employees of the importance of quality and the serious consequences of poor quality. The work environment is safer and as a result employees are more ready to report deviations and failures in production, and assume responsibility for any errors or deviations.

A remarkable improvement was measured in implementing the key quality behavior success factors and a corresponding quality language was developed to express the new quality culture ideas, values and priorities.

•Is it right time to think and act on quality culture?

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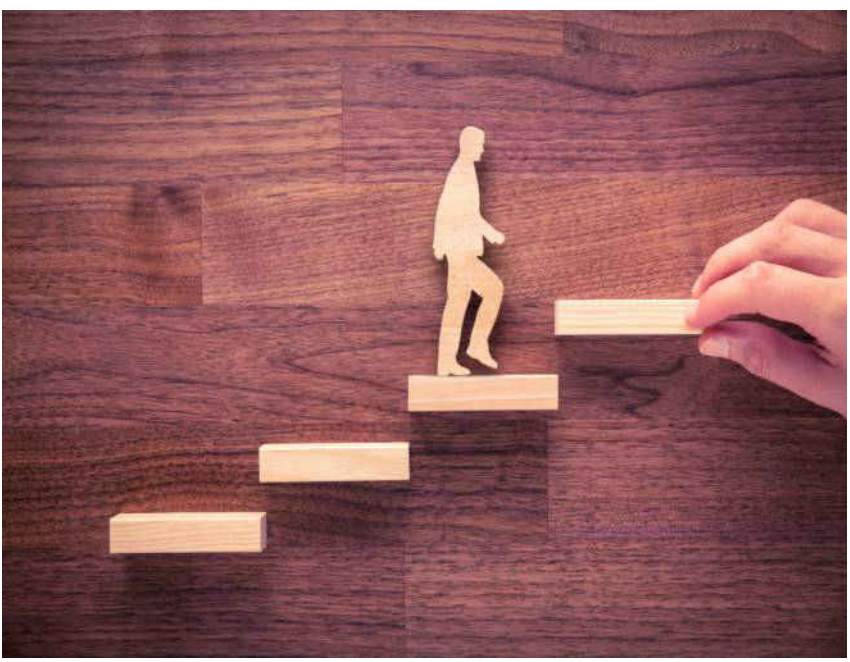
About the Author:

Mr. Eli Laniado is CEO and Founder, Laniado Group; specializing in organizational development and management consulting. He is having 20 years of experience in the areas of organizational-culture, communication and marketing. He is well-known among corporate clients as operational consultant who works hand in hand with company staff to ensure successful implementation of the projects. Clients include leading international and Fortune 500 companies such as Teva Pharmaceuticals, SUN Pharma Industries, Strauss-Group International, Bank Leumi, Applied Materials Inc., Israel Electric Corporation, and others.

BRIC By Brick



The pharma industry has been in the forefront of the discovery, development, production and marketing of medications. Earlier years we observed that the developed countries, such as the USA, Japan and European countries were the top growing markets in pharma industry. Well the scenario is changing and thanks to the growing economies of countries like Latin America, Europe, India, China as well as improved health expenditures and life style in developing nations which is leading to shift the pharma market.- By Ms. Titiksha Shinde

Introduction:

The global pharmaceutical sector represents market value of nearly one tr. USD. The North America and Europe are the largest global markets for pharmaceuticals and includes following companies Pfizer, Merck and Johnson & Johnson from US, Novartis and Roche from Switzerland, Sanofi from France, etc. In 2017, the United States generated more than 450 bn. of revenue the largest pharmaceutical market; Europe generated around 214 bn. U.S. dollars. The rest of the global pharmaceutical revenue is mainly generated from emerging markets which include countries like Brazil, Russia, India and China (BRIC). Latin America and the Indian Subcontinent are the only world regions for which predicted CAGR is higher than 10 % until 2018. BRIC countries signify 40% of the total world's population. Those countries highly rely on prescription drugs. Growing population and rising prevalence of chronic diseases are some of the key factors leading to growth of BRIC.

Top therapeutic classes and drugs:

Growing therapeutic segments include cardiovascular, diabetes and oncology drugs due to hike in incidence of non-communicable diseases that imitates the western lifestyle. Diabetes and oncology is estimated to grow by more than 20% by 2030. Well the challenges can be summative in three sections- infrastructure development, cost-containment policies and value-driven drug evaluation.

In 2017, the top therapeutic class based on revenues is Oncologics that generated 81 bn USD, pain therapy- 76 bn USD, and anti-diabetics- 72 bn USD. Amongst the oncologic drugs for non-small cell lung cancer and breast cancer were foremost in therapeutic drug development. Instead, drugs that are used for treating depression like Cymbalta generated 36 bn USD of revenue worldwide. One more popular medicine that generated revenue of 5.8 bn USD in 2015 was Bristol-Myers Squibb's –neurology product Aripiprazole marketed as Abilify.

The graphics below shows the share of Pharmaceutical revenue worldwide in 2017. The major shareholder is USA 33%, further followed by 15 Western European countries which held a share of 22 %.

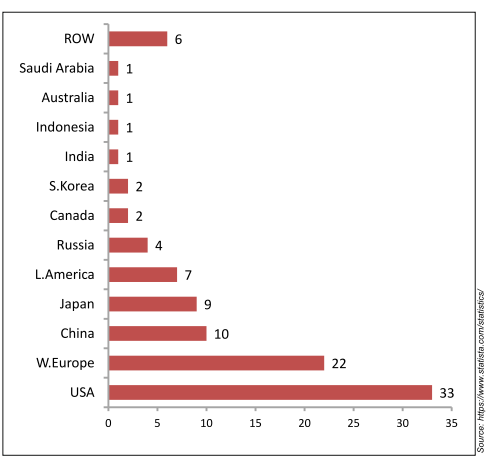


Figure 1: % of pharmaceutical global revenue

BRIC- emerging markets:

As per the Economists the emerging markets will result in high income with well managed growth strategy, competency and scalability. It was observed that the sales of the pharmaceutical markets are doubled in period of five years in BRIC countries with a market share of approximately 20%. The pharma market seems to be growing because of key reason such as growing population, adoption of western lifestyle, increasing life expectancy and saturated pharma market in developed nations. Further there is rapid growth observed in market and research in BRIC countries leading to migration of economic and research activities from Europe to pharmemerging countries. In 2016 the Brazil and China grew by 10.0% and 6.9% respectively, compared to an average market growth of 4.5% for total EU market and 6.3% for the US market.

Emerging countries poses firm market for launching new products. Niche products can surge the profits and BRIC poses attractive market for investments, increasing income, availability of human capital and low cost wages. Other advantages of emerging market in comparison to developed countries are cost of R&D is low, clinical trials are cost effective and drastically reduces the cost of drug development. Thus it impacts positively on Return on Investment (ROI).

Foot print of BRIC:

Basically the BRIC countries can be fragmented into two groups based on their way towards globalization. China & India are taking benefits of globalization march by integrating into global supply chains. Brazil & Russia are taking advantage of globalization to sell their natural resources.

Brazil: The Brazilian Health Regulatory Agency's (ANVISA's) is the regulatory agency and is trying to cut down the timelines of review for Marketing Authorization Applications (MAAs) and post-marketing changes. Also, the Health minister, Arthur Chioro and the National Health Surveillance Agency on 27 February announced a set of measures for adjustment and regulation of the pharmaceutical market, with actions to accelerate the registration of "clone" medicines.

The present day criteria are meticulously customized to the Brazilian pharmaceutical market and they furthermore escalate the competition. The modifications aim to keep the average percentage of adjustment below inflation. In addition, a fixed date for disclosure of each of the factors will give greater transparency to the process. This new methodology is expected to drop the price adjustment percentage, thereby decreasing healthcare expenditure by approximately BRL100 mn (USD 35.3 mn) per year.

The Drug Market Tracking system initiative will enable measurement of the prices adopted in the private and public market, giving further precision in public policy development for the pharmaceutical industry. It will be attainable, to measure the impact and monitor trends faster and observe the pharmaceutical market behavior and effects of the new price-adjustment methodology.

70% volume of pharmaceutical market is dominated by domestic players and in

terms of value, big pharma companies contribute to about one-half of the market. Tie up with local players can help in efficient building of the organization in country. Well MNCs have to take the challenge to compete with local companies. Government's strategy is to regulate the pricing of pharmaceuticals to make high cost branded drugs affordable.

Russia: In the pharmaceutical industry, despite the flaws in industry regulations and insufficient governmental funding in certain areas of Russian economy and market challenges, there is general optimism about growth prospects. This optimism is emphasized in several ways, including the construction of manufacturing facilities in Russia and the establishment of alliances between foreign and Russian companies. Russia's dependency has been totally on imported drugs and APIs, and up to 75% of all drugs on the Russian market in monetary terms are imported.

To pacify the situation, the Russian government adopted a Pharma 2020 program aiming to reduce the ratio of imported drugs by 2020 to 50%, and for essential drugs to 10% of the total number of items. A resolution was issued by the government in November 2015, curbing acquisition for state and municipal needs of foreign medicines included on the list of the most important and essential drugs, known as the EDL list. The essential drug list is designed such that it covers elderly, differently abled, children's and pregnant ladies in the population.
Over the past years, some pharmaceutical companies have established partnerships with Russian-based companies and built joint manufacturing plants. Almost 20% of the medicines are imported from abroad and are freely available in hospitals. The government is insecured with its dependence on imports and state of underdeveloped local companies. The government aims to roll out an import substitution strategy so that local drug manufacturers cover one-half of the generic drug market.

India: India is selected as 3rd most **preferred destination for pharma business** with competitive score of 6.3 because of its tax environment, staff quality, infrastructure, research capability, & labor costs. India is rated by pharma organizations to have twice the potential as compared to western countries; it is also ranked second with score of 7.0 whereas first ranker is china with the score of 7.2; overtaking the countries like US (6.3), Korea (6), and Germany (5.9). In terms of **"quality and knowledge"** also India is ranked above the China, Korea, & Spain.

The sensitivity of India's **API manufacturing** is taking shape. As per the survey, the industry considers India to be competent than Italy, Spain, and Korea; however it lacks efficiency in comparison to developed nations such as Germany and the US.
If we have a glance at exhibitor number, it is increased by more than 200 companies as compared to 2017 vent which featured 1400 exhibitors from 100 countries. The analysis of domestic respondents revealed that the majority (80%) were "confident" or "extremely confident" in their business outlook for India's market in 2018. The CPhI report also revealed that 88% of respondents in India were dedicated to work with international players in 2018.

Well, Indian firms are expanding their overseas business of generic drugs. Some organizations have already established manufacturing facilities that meet the countries regulatory standards. Some organizations have also begun partnership

with foreign pharmaceutical firms for ease of assessment and distribution.
China: The government's recent investments in healthcare are leading to develop the strategies for the domestic market. The domestic market is highly fragmented across 5000 domestic manufacturers that export APIs. Their production of final products, mostly generic medicines, is known for low quality. Promoting collaboration and technological exchange among domestic firms and big pharma by providing a favorable legal environment, liberalization of drug prices and offering excellent conditions to highly qualified citizens is the new policy. China's healthcare reforms have increased healthcare expenditures, leading to growth and building second largest domestic pharmaceutical market in the world. Top 10 MNCs have invested between 3 bn $ and 9 bn $ capturing 20% of big pharma market.

Life science is their priority to develop research and hence the China government is promoting the policy to encourage collaboration and technology transfer amongst local and big players. The government is taking initiatives to decrease the cost of medicines and make them affordable by implementing stringent tendering process at central and provinces levels to reduce the malpractices. Since, 2011 the pharmaceutical expenditure has been grown and rise in prices is decreased to just 1% in 2016. To overcome this downward pressure on prices, the government is looking after new drugs from MNCs and is trying to smoothen the approval process which usually takes 7 years.

New leads to target:

Age-related Macular Degeneration: Pharmaceutical sales in the Age-related Macular Degeneration market (AMD) were estimated to be 4.9 bn USD across seven major markets of USA, France, Germany, Italy, Spain, United Kingdom, and Japan. Global data predicts the launch of three drugs for the treatment of dry AMD (dAMD) - geographic atrophy (GA), and three late-stage pipeline drugs for wet AMD (wAMD). In particular, growth driver will be the drugs to treat dAMD as currently no prescription medications are available for these patients. New drugs that are entering in dAMD market includes two anti-compliment agents Apellis' APL-2 and Ophthotech's Zimura, and one neuroprotective agent, Allergan's Brimo DDS, which together will drive an increase of the treated AMD cases, expanding the AMD market. The market is expected to reach 11.5 bn USD in 2026, at a remarkable CAGR of 8.9 %.

Cancer cachexia: The market for products to effectively support care in oncology will increase in the next decade with longer life scale. Thus the need for supportive care will increase to improve patient quality of life, and chances of completion of treatment. There are various gaps present in supporting the cancer treatment but major gap is observed with cancer cachexia – an indication showing symptoms like weight loss, anorexia, asthenia and anemia. The Chemotherapy-Induced Nausea & Vomiting (CINV) features a wide array of treatment options but it lacks blockbuster drugs, Oral Mucositis has very few treatment portfolios and cancer cachexia has no approved treatments. Presently there are no approved products by the regulations like FDA, European Medicines Agency. Comprehensively the unmet need in this indication is simply for any therapy to treat it.

Conclusion:

Overall, from the perspective of emerging nation Brazil represents opportunity for mergers and acquisitions deals. Russia presents as a willing nation in wellness with almost half of the market dominated by big pharma companies. Indian government offers opportunity to MNCs but the climate is competitive in between quality of the branded generic and newly branded pharmaceuticals. China represents the opportunity to develop robust market share, skilled labors and manufacturing capability. The risk that they impart is in case of transfer of technology in exchange of market access.

To take this forward there is need for Indian pharma industry to promote new thinking, innovations of new molecules, transfer of technology and provide accessibility. Various domestic players export essential drugs to developing as well as developed nations at affordable prices. Many manufacturing plants are USFDA approved and have efficient production and technology facilities to ensure smooth access to the essential and good quality medicines. This would supplement the capability of Indian generic pharmaceutical enterprises to meet the supply demands at National and International levels. These interconnecting concerns on access to medicines, technology transfer and local production have resulted in growing attention to the possibility of international cooperation to enhance accessibility, technology and production.

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About the Author:

Ms. Titiksha Shinde - Sr. Research Associate of Interlink Marketing Consultancy Pvt Ltd; is a Pharmacy Graduate from Mumbai University and post graduate in Pharmaceutical analysis from Bombay college of pharmacy. She has been working with Interlink since last one and half year and is activity involved in management of pharmaceutical projects and in-house publication Interlink Insight.

Thinking Fresh

Patient Experience - TMR Way

Improving patient experience can help hospital improve its financial performance by strengthening customer loyalty, building reputation and brand, and boosting utilization of hospital services through increased referrals to family and friends. Target-Measure- Review model in hospital set up can ensure a positive patient perception to increase loyalty & brand building and can lead to smooth patient flow, thereby increasing hospital productivity & turnover. By - Interlink Knowledge Cell

Introduction:

Realizing the fact that Hospital is more than a business imperative service to patients and families and supporting them morally at the most challenging and critical times of their lives are our duty. Apart from keeping patient informed and engaged, mollifying the censorious environment, and ensuring that the patient feels supported at their stress times helps accelerating the healing process. This leads to improving their experience and creating positive brand image.

The process of creating good perception of the organisation starts from a very starting point when patient or family approaches the organisation, thus role of receptionist is in influencing and providing embossing guidance. The present business phase is the customer dependent age, and customer is considered as the king. It is essential for every organization to keep its consumers satisfied by providing excellent quality service and value and maintain in the competitive market. Thus, customer satisfaction is the keyword in today's powerful competitive business world.

Care model design:

Care model can be designed in such a way that it remains seamless, profitable and enhances patient/ consumer experience. At each touch point, patient experience is crucial.

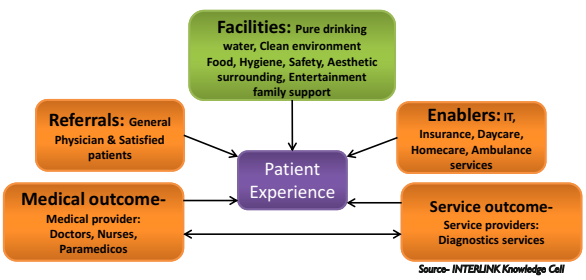

Figure 1: 5-Touch point care model

5-Touch point model:

Healthcare is developing day by day and providing access to maximum number of population in lower cost is today's objective. Adoption of new technologies, medications, approaches have altered the way of delivering care. The old saying, "If you don't create change – change creates you" applies over here. The care model represents the various ways by which the healthcare services are provided. The referrals provide insights and direct the patients towards medical and healthcare services. The medical providers like doctors, paramedical staff, provide medical services to patients and service providers including diagnostic services, blood banks, and pathology labs provide service outcomes while treating the patient. In addition to the services the surrounding environment and facilities available in the hospital plays a major role. Facilities like pure drinking water, food canteen, clean and hygienic environment, entertainment, aesthetic surrounding, and availability of essential requirements to support family members leads in creating positive image of the system. In addition to these basic services, health Insurance to take care of bills, daycare services, homecare services, ambulance services with life support and medical staff in emergency cases, robust IT services in supporting the services and

technologies are playing the role of enablers in healthcare system.

The keys to attract and influence the customer:
The parameter that attracts the patient apart from the treatment is the services, facilities that satisfies their needs and provide comfort. The key points that patient will look at in the hospital system includes appropriateness (relevant to patient care), timeliness, efficacy & effectiveness (right treatment at right time), Safe & clean environment, digitalisation to make process easy.
The basic elements that HCAHPS (The Hospital Consumer Assessment of Healthcare Providers and Systems) are tracking covers the points mentioned below. The personal effort by everyone at the facility incorporates good customer service. Some items listed such as clean rooms and quiet atmosphere can be improved by administrative policies and protocols.

In order to really meet and exceed the expectations of customers from diverse communities, it is important to learn and practice the basic principles of customer service:
- Staff has to be respectful, courteous and polite
- Make the customer feel welcome
- Give your undivided attention and time when interacting with customers
- Be friendly & learn about the cultures in the communities you serve
- Develop excellent communication skills with patients and families to bridge language and cultural barriers
- Appreciate the value of the customer's time
- Develop excellent communication skills with co-workers
- Be dependable/ credible
- Make the extra effort to build relationship with customer

These basic principles will let patients know you care, that they are not just another number, and that their business is invaluable.

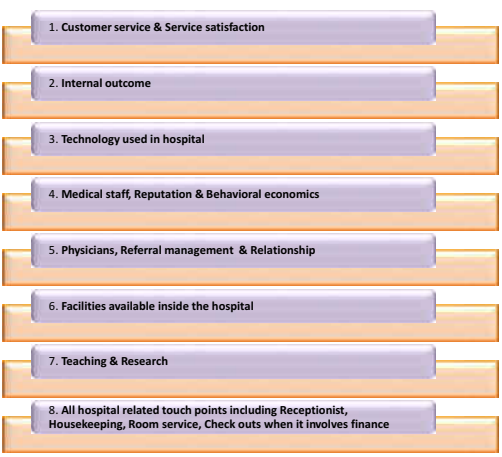

Figure 2: Key platforms to improve patient experience

Four enablers:

1. Waiting period:
Reduction in waiting times operationally and implementing self-service kiosks to

speed up the registration process and is found to be associated with higher patient satisfaction.

Some distractions like televisions, Wi-Fi or garden area, for children's' play areas helps to reduce patient anxiety. Depending on the majority of customer age group the nature and content of the distraction can be chosen. For example, educational posters displayed in waiting rooms will impart knowledge and educate the people thereby providing distraction from waiting time period.

2. Digitization:

Digitization is enabling centralized database that would contain all aspects of patients' health, reducing the errors, and making processes easier. By going digital, delivery of healthcare services can be made flexible and efficient beyond the brick and mortar constraints of traditional medicine. The power of digitization in healthcare is observed in eHealth, which is a part of the government program of Digital India. Other online processes like e-Pharmacy, e-Diagnostics, e-Insurance, e-Referrals, would provide a robust ecosystem support to the patients and service providers. The inconvenience resulting due to registration and other formalities can be tackled by merely identifying themselves through the aadhar number.

3. Behavioral Economics (BE):

The principles of Behavioral Economics (BE) can be related to the social aspects of healthcare. Patient-related decisions which often involve a certain amount of risk, an understanding of which can be benefited from BE. The doctors can help patients to make informed decisions by offering clear comparison. Example-Giving feedback to patients on how they are reacting to treatment and what is the progress, will motivate people towards treatment & effectively trigger a desire to change behavior and improve to do better than average. This has been used, to convince patients to quit smoking, by giving them feedback on the 'age' of their lungs.

4. Impact of technology:

Technology will help in reduction of healthcare costs by allowing clinical staff to remotely work together and instantly access patient data. This will serve a growing population of patients to allow physicians to remotely monitor the chronic illnesses and patient's longterm health & out of hospital care. Improvisation in diagnoses by bringing together data from disparate devices

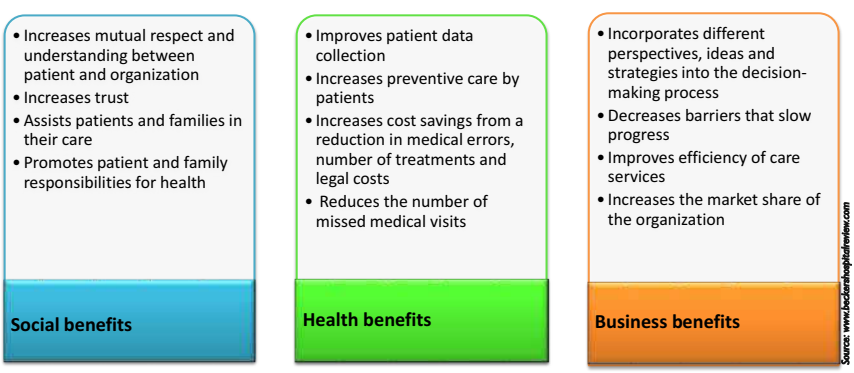

Figure 3: Benefits of aligned customer services

(e.g. monitors, images, therapeutic devices) over time to form a complete picture of a single patient's health status. Improve medical equipment functionality and maintenance of equipment's. Significantly improves the functioning of healthcare ICT systems by improving information sharing wirelessly. Monitor the consumption of medicines on time. Reduce the time to settle the insurance claim and admission for insured persons. Transform the data generated in an ambulance during the transit to the hospitals and doctors in real time, thereby making the emergency care more efficient. In most of the cases, the ambulance and the ICT system of hospitals have difficulty in integrating and exchanging information.

Designing the processes to streamline the healthcare services technology is bringing a revolutionary change across healthcare sector. Telemedicine to reach to rural communities, technology is making way forward into every aspect of healthcare and making efforts to address major challenges.

The benefits that organization will gain from systematic and aligned customer services are mentioned below.

Degree of maturity in hospitality:

•Lean management applied in healthcare aims at boosting productivity, improving customer and employee satisfaction thereby reducing the lead time. Analyzing the current situation of the hospital and to assess the suitability of lean activities is essential. As per the needs and requirements of the hospital optimizing the goals, methods and accompanying change management can be carried out. This ensures the success of lean hospital projects and sustainability. Lean hospital management offers leaders many possible ways to establish professional, process-driven health care organizations

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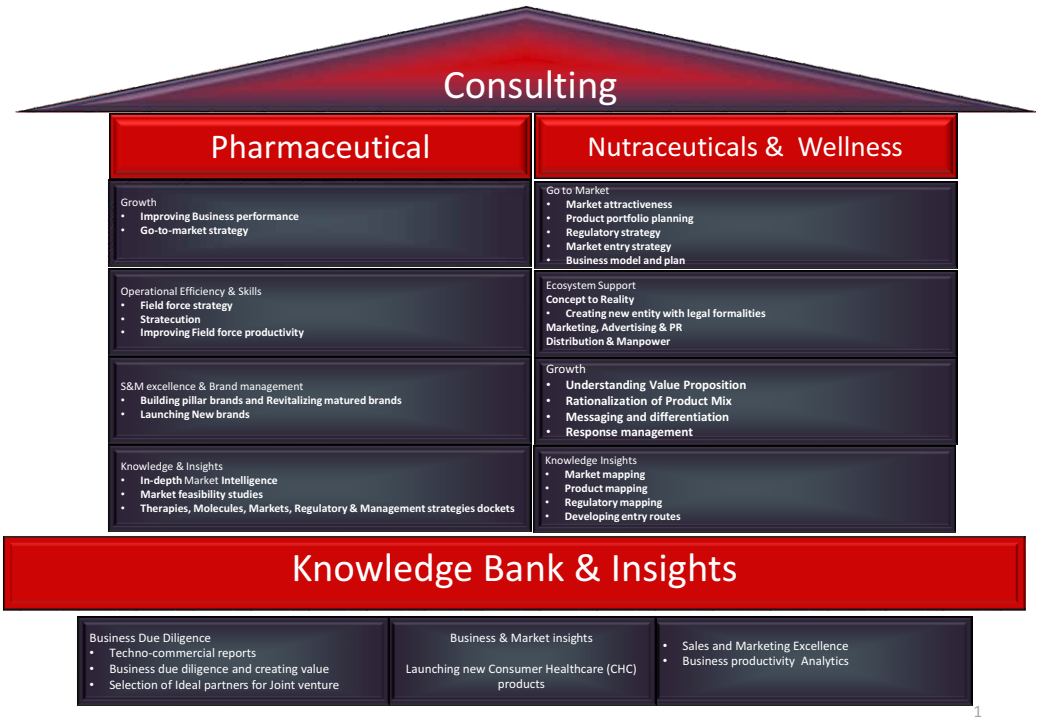

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