

InterlinkInsight

Perspective For Business Performance

QUARTERLY VOL. 19 | ISSUE-3 | JANUARY 2021

**PHARMA
NUTRITION**

A NEW **WAVE**



NEW YEAR ISSUE 2021

FROM THE PUBLISHER'S DESK



Dear Readers,

Last eight months our work culture has undergone an enormous change which leads every management to reflect and workout its flow of operations by overcoming this disruption for better future.

Keeping these elements in mind, Interlink Alumni team and others who have been experienced Interlink Services are the authors and co-authors of this recent issue.

Having crossed 36 years in Training and Consulting in India and across the Globe, we have learnt that at the end '**Performance Counts**'.

Obviously, each piece of this **Interlink Insight** issue would provoke you to think differently to look at your business to improve productivity.

A new concept of **Pharma- Nutrition** has been depicted on cover and also makes you think whether this 'Co-option' of Pharma and Nutrition would lead the way for tomorrow or not!

Respond to the existing change and also to this Insight issue!

Enjoy your reading.

Dr. R. B. Smarta
Chairman & MD

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Hope of Good Health: Pharma-Nutra



November, being a nutrition month in India, it is important to look at an amazing combination of two co-existing synergistic way to treat life for its fullness. Pharma-Nutrition as a subject by itself, considering one is not complete without other part in bringing wellness to life. Hence, it is that amazing combination where prevention, cure and wellness of patient are taken care of. -
By *Dr. R. B. Smarta*



Pharma-Nutrition in New Normal Era:

Pharma is transiting from Medicines to Food for Special Dietary Use (FSDU) to Pharma Nutrition as the food has various dimensions and each country has its own food habits. It may be fully nutritionally balanced or there could be a total lack of it.

Nutrients are best available through food and how it is cooked, use of oil, fats and the spices are used. Food occupies a significant role in Health. Health domain in next normal era is likely to witness significant changes across the world.

Beyond that it is a matter of palate and organoleptic senses issue. Few may live life with burgers and aerated drinks, few may have their own ways.

However, obesity in childhood and Diabetes in younger age makes us feel that there is a need of something like Pharma – Nutrition.

Pharma- Nutrition Convergence:

Father of medical practise Hippocrates has already said that “Food be thy medicine, Medicine be thy Food and walk a mile....” which is a powerful message on the medical practise all over the world. A step beyond, traditional Indian medicines, provide a three cornerstones formula for fullness of health!

1. Ahar

2. Vihar

3. Aushadhi.....

Essentially Diet, Exercise and Medicines!!

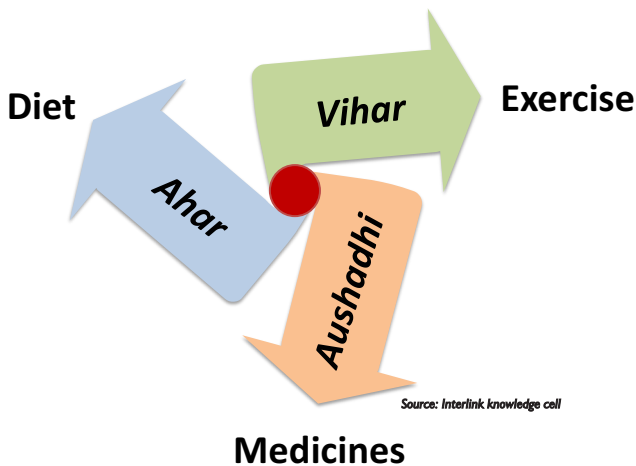


Fig. 1.1: Pharma Nutrition Convergence

To effectively respond to viral infections, pharmaceutical products can repair the inflammatory and degenerative regions that degenerate in the respiratory tract and restore homeostasis of the metabolic processes. Simultaneously, nutrition and micro-nutrients continuously build up immunity of the same patient. Is it not **Pharma-Nutrition has symbiotic effect to make patient healthy?**

Other way round also, immuno-protection is the corner stone of the medical practise. The preservation of the immune system is the strategic measure of public health in social and clinical management of life-span extension world-wide.

Growth and Opportunities for Pharma-Nutrition:

A. Technology Influence:

On one hand as a result of fermentation technology there are ways of creating plant products and on the other hand scientists are taking help of making the nutrients available in precise quantity as per individual need.

One is acting at developmental stage and the other one is looking at designed quantity for the patient!

It is during the knowledge dispersal stage where cross-disciplinary excerpts carry out joint research in time. Like economy is going towards “Shared Economy”, research is also moving towards “Shared Knowledge” and insights to shorten time and makes a meaningful contribution which in turn leads to technology concurrence.

B. Human Microbiome:

Pharma - Nutrition concept should aim at searching its soul in human microbiome. More insights from human microbiomes would generate more solutions for human beings.

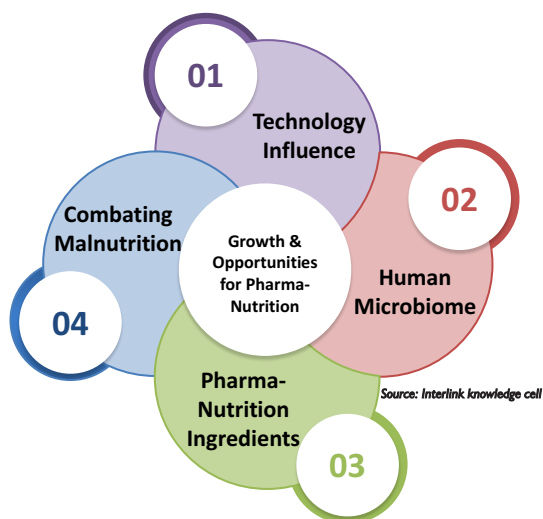


Fig. 1.2: Growth and Opportunities for Pharma-Nutrition

C. Pharma-Nutrition Ingredients:

The fullness of health approach should be derived from the strengths of both disciplines. Strengths of pharmaceuticals industry for its R&D capabilities, defining quality, safety and efficacy as well as standards of each molecule or evidence-based nature of discerning product can be combined with nutraceutical strengths of

nutrition, clinical nutrition, biochemistry, bioavailability, bio markers, to ensure wholesome health progress. Several bioactive compounds including fibre, secondary plant molecules, friendly bacteria, essential fatty acids, probiotics and prebiotics can be manufactured with promising value proposition.

Moreover, many pharma molecules are extracted from natural plants or by technology which humans can use as medicines or as nutrients. Vitamins, minerals, curative and prophylactic solutions have been derived from many such combinations.

Nutraceutical molecules like Lutein, Lycopene, Zeaxanthin, Spirulina and others have in-built properties to prevent and also cure few medical conditions.

Optimal health and elimination of chronic disease can be accomplished by this combination.

D. Combating Malnutrition:

It is perceived that a number of modern diseases are linked to poor diets and the concept of “malnutrition”, even in those who are getting sufficient quantity of calories and lacking proper balance of several food ingredients such as amino acids, peptides, minerals, etc. Furthermore, there is budding evidence to indicate that definite nutritional balance through supplement can preserve patient health beyond widely used medicinal treatments.

Emerging Issues:

The new 'Pharma-Nutrition' has to face five major challenges:

1. Education to healthcare providers
2. Difficulty in patenting the products
3. OTC prone nature of Nutraceutical products
4. Prescription limitation of dieticians and nutritionists
5. Belief system of HCPCs

Pharmaceutical companies will learn to collaborate for benefits of patient's health. Nutrition companies need to improve their research and development to enhance their scientific capabilities as well as building key relationship with drug companies and practitioners.

New Landscape:

Pharma-Nutrition may not be a concept in practise as it is observed that majority of specialities have the tendency to provide nutrition benefits to patient at a particular function where they feel it's better to provide some sort of strength to the patient. Modern medicines usually focus on single target condition and provide entire relief or cure, irrespective of its effects on other organs. On the contrary, the multi-target medicines (Pharma-Nutrition) may be used in synchronised way to provide maximum benefit to patient.

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About Author:

Dr. R. B. Smarta, Founder and Managing Director of Interlink Marketing Consultancy Pvt. Ltd. Being a thought leader in Pharmaceutical, Nutraceutical and wellness industry, he has been contributing globally through Interlink Consultancy and building business performance of his clients for 33 years. Having a Master's degree (M.Sc.) in Organic Chemistry in Drugs, MMS in Marketing, PhD in Management, and FRSA (Fellow of Royal Society of Arts) London, he is-perusing his passion of converting science to Business. Besides being a consultant, he has been teaching at IIM, prestigious management institutes, Pharmacy College, Pharmacists Associations, guiding PhD students and written as many as 7 Books on Management, Pharma, Nutra, Foods domain, and many articles in prestigious journals/magazines.





Harnessing Reforms-Pharma



*Post first world war, as India was largely dependent on Import of modern medicines, the Indian Market was flooded with adulterated, spurious and sub-standard drugs. This resulted in appointment of Drug Enquiry Committee under the Chairmanship of Colonel R. N. Chopra in August 1930. The committee, in its report submitted in 1931, recommended for enactment of a comprehensive all India legislation for the control of drugs and pharmacy either as a combined Act or a separate Drugs Act and Pharmacy Act. Thereafter, comprehensive Drug Act was enacted in 1940. -By **Mr. N. M. Gandhi***



Regulatory Progression:

The main object of the Act was to prevent sale of substandard drugs and maintain high standards of quality of the medicines. Therefore, in addition to the requirements for the quality compliance and their strict adherence, there had to be sufficient deterrence for non-compliance. This could be achieved by providing stringent penalties to the offenders. The rules to the said act were notified by the Central Government on 21st December 1945. During the course of the enforcement of the act depending upon the needs the act's scope was also widened.

The regulatory reforms can be discussed in three areas. First with respect to the scope of the act and rules, second with respect to the requirements as to achieve quality and third about the enhancement of penalties.

I. Scope of the Act – As per the experiences the scope of the legislation was widened as follows;

a. There were instances of adverse reactions and toxicity due to use of cosmetics such as deodorants, pomades, lipsticks and nail polishes. The raw materials were not being tested and hygienic conditions in cosmetics manufacturing were not being observed. The Central Council of Health opined that the manufacture of cosmetics should be regulated by extending the provisions of the Drugs Act, 1940. Therefore, the act was amended to include regulations regarding the manufacture of cosmetics and prohibition of import and sale of sub-standard and misbranded cosmetics vide the act 21 of 1962. Hereinafter, the act was called the Drugs and Cosmetics Act, 1940.

b. Initially, definition of 'drug' under Section 3(b) of the Act was excluding medicines under Ayurvedic or Unani systems. Due to commercialisation of Ayurvedic and Unani drugs by the firms and many preparations contained partly modern drugs and partly Ayurvedic drugs, it was difficult to regulate them. Udupa Committee finding disclosed that costly raw materials such as gold, musk, pearl, saffron, etc., claimed to be the ingredients were actually either not used or substituted by imitation products. By the amending the act 13 of 1964, the definition of drug under section 3(b) was thus amended and definition of Ayurvedic drug was also included under section 3(a) of the act. The Ayurvedic drugs were thus brought within the purview of the act. Further, separate chapter IVA was inserted for the purpose of regulation, prohibition, powers, cognizance, penalties, etc. with respect to Ayurvedic, Siddha and Unani drugs.

c. The definition under Section 3 (a) was further amended to cover disease and disorders in animals with respect to Ayurvedic, Siddha and Unani drugs by amending the act 68 of 1982. Also by the said amended act, components or excipients used in manufacture of drugs and devices as notified by Central Government were brought under purview of Drugs and Cosmetics Act, 1940.

2. Requirements as to Achieve Quality – The rules to the said act have been amended several times to provide for various quality concepts evolved from time to time. Some of them can be summarized as follows;

a. The conditions of licences are imposed with respect to the additional precaution to be taken while sale or distribution of Schedule H, H1 drugs as provided under rule 65 of the said rules, 1945.

b. Concept of dual licensing introduced for certain category of drugs such as LVPs, Vaccine, Sera, Blood Centers, rDNA derived drugs, etc.

c. Submission of result of bioequivalence study of oral dosage form of drugs specified under category II and category IV of the biopharmaceutical classification system, while applying for product licence. Further, it was also made mandatory to submit the evidence and data justifying for the applied drug products about safety, efficacy, stability, etc. and have approval of DCGI.

d. The provisions for Good Manufacturing Practices (GMPs) and requirements of premises, plant and equipment for pharmaceutical products was inserted as Schedule M on 12th June 1987. Thereafter it was upgraded to the global standards on 11th December 2001. Now after about 19 years these provisions are further required to be upgraded to the current global trends.

e. Schedule M addresses the requirements for the quality control and testing laboratory. But comprehensive requirements are now prescribed under Schedule LI for Good Laboratory Practices (GLPs) and requirements of premises and equipment in laboratory from 1st November 2010.

f. In view of the exhaustive developments in the area of medical devices concerning their safety, performance, evaluation, standards, classification and specifications and need to regulate the predicate devices and diagnostic devices Medical Devices Rules, 2017 have been made effective from 1st January 2018. The definition of medical devices is widened to cover almost all the medical devices and diagnostic medical devices by notification dated 11th February 2020.

g. There were concerns and incidences reported in clinical trials. Therefore, there was need to provide comprehensive regulatory frame work for new drugs and clinical trials. It dealt comprehensively about the ethics committee, clinical trials, Bioavailability and Bioequivalence study, requirements for investigational new drugs, compensation in case of injury or death of the trial subject, imports of new drugs, APIs, etc. In view of this New Drugs and Clinical Trials Rules, 2019 were notified and were effective from 19th March 2019.

h. The products are developed by the research and development teams of the

companies. There is trend of technology transfer and getting the products manufactured on third party contract or principle to principle contracts from the contract manufacturers. The products are being marketed by the marketers. Now vide notification dated 11th February 2020 the marketer who sells or distributes drug shall be responsible for the quality of the said drug and for the regulatory compliances thereof This will be effective from 1st March 2021.

3. Enhancement of Penalties – The nature of punishment by way of fine and imprisonment was amended from time to time. The graded punishment was introduced and punishment was prescribed for different offences. The penalties were enhanced as per the current status from time to time by following amendment acts.

a. Act 11 of 1955 – Punishment was enhanced from one year to three years and removed the limit of fine of ₹.500/- prescribed earlier.

b. Act 35 of 1960

c. Act 13 of 1964

d. Act 68 of 1982

e. Major changes with respect to punishment were made by the Amendment Act 26 of 2008 (w.e.f. 10th August 2009). The amendment was based on the recommendations of the Expert Committee on examining the drug regulatory issues and problems of spurious drugs under Chairmanship of Dr R. A. Mashelkar. The punishment was enhanced to life imprisonment for offences related to spurious drugs leading to grievous hurt and fine is also enhanced considerably for all the offences under Section 27. The punishment is also enhanced for the subsequent offences. The amended section 27(a) has incorporated a unique provision which provides that fine imposed on the convicted person and realized under the said clause shall be paid to the person who used such adulterated or spurious drug and in case of his death to his relative.

As per the said amendment Act 26 of 2008;

a. The offences under Chapter IV are to be tried by the Court of Sessions as against earlier provided by the Metropolitan Magistrate or Judicial Magistrate First Class.

b. Provides for setting up or designating Special Courts for certain offences under section 36AB of the act.

c. Offences related to spurious and adulterated drugs are considered as cognizable and non-bailable as specified under section 36AC of the act.

4. The regulatory reforms is a dynamic process and amendments are proposed as the time demands, either demanded by the stakeholders or due to scientific and technological advancements. The following regulatory changes are expected in near future.

a. The provisions related to the requirements of building, premises and Good Manufacturing Practices is proposed to be upgraded and the draft rules are already notified vide GSR 999 (E) dated 5th October 2018. It is proposed for major change in the quality management systems and will be at par with the global regulatory requirements including those of the developed countries.

b. As like Medical Devices Rules and New Drugs and Clinical Trials Rules, complete new set of separate rules under Drugs and Cosmetics Act, 1940 is proposed for cosmetics as Cosmetics Rules, 2018. The draft rules are already published vide GSR No. 1153 (E) dated 29th November 2018. The rules are comprehensive for the import, manufacture of cosmetics, GMP, GLP, and have provided for permissions for new cosmetics.

c. Separate part is being proposed for “Sale of Drugs by E-Pharmacy” under Drugs and Cosmetics Rules, 1945. The draft rules are published for comments and suggestions vide GSR No. 817 (E) dated 28th August 2018. The e-pharmacy, e-pharmacy portal, etc. are defined and the registration of the e-pharmacy portals is proposed by the Central Licensing Authority for recognizing the online sale of medicines. Check and balances are proposed under the conditions of registration.

Conclusion:

It will be clear from the status of the regulatory reforms that the changes and reforms are inevitable whenever there is change in current trends or due to scientific and technological developments. The changes in provisions act as a guidance and enables the entrepreneurs to plan and execute their projects. They also ensure confidence in the customers, international buyers and consumers as well.

About Author:

Shri. Nilesh Gandhi is a graduate in pharmacy and law. He has also acquired Diploma of Computer Application, Post Graduate Certificate in IPR – TRIPS and one year program in Good Management Practices specifically conducted for regulatory officers.

After working for four years in pharmaceutical industry, he joined Food and Drugs Administration, Maharashtra State as Drugs Inspector in 1992 and was promoted as Assistant Commissioner (Drugs) in 2015. He has jointly authored an Exhaustive Commentary on Drugs and Cosmetics Act, 1940 and Rules, 1945 including Medical Devices Rules, 2017, New Drugs and Clinical Trials Rules, 2019, Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 and Rules, 1955 and Drugs

(Prices) Control Order, 2013. After 26 years of fruitful and satisfying service in FDA, Maharashtra, he has opted for voluntary retirement. After his retirement, he is associated with Pharmalex in providing complete legal solutions and other services such as technical and regulatory compliance audits, gap analysis, trainings, drafting regulatory responses, etc. for the pharmaceutical industries and distributors.





Harnessing Reforms - Nutra



*Nutraceuticals and nutrition foods, though popular in other parts of the world, was a new concept in India when FSSAI started functioning on 5th August, 2011. USA, Europe, Japan, China and other developed nations were the only consumer of Nutraceuticals and Health Supplements. It was used mostly by the health conscious consumers who are affluent also. With passage of time, these products find acceptability among a larger chunk of the health conscious populations. Credit goes to the medical professionals and nutritionists who advocated consumption of nutraceuticals and nutrition products. FSSAI has also notified Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food Regulations, 2016. Since the regulations was new not only to the Food Business Operators (FBOs) but also to the Food Safety Officers (FSOs), enforcement of the regulations was effective from 1st January, 2018. While implementing the regulations, a number of short comings have been noticed and need of the regulatory reforms has been discussed. -By **Dr. Pradip Chakraborty**.*



Recommended Daily Allowance for Indians (RDAI):

As per Section 22(1)(a)(II), foods for special dietary uses or functional foods or nutraceuticals or health supplements may contain minerals or vitamins or proteins or metals or their compounds or amino acids (in amounts not exceeding the Recommended Daily Allowance for Indians) or enzymes (within permissible limits). RDA is different for different countries. USFDA have both minimum and maximum RDA whereas in India, we have no maximum and minimum limits.

Indian Council of Medical Research submitted a report of the expert group in 2010 to update the nutrient requirements and dietary allowance for Indians. FSSAI also adopted the RDAI recommendations of the National Institute of Nutrition - Indian Council of Medical Research (NIN-ICMR), Hyderabad. Quantity of nutrients added to the articles of food shall not exceed the RDAI as specified by the ICMR and in case such standards are not specified, the standards laid down by international food standards body, namely Codex Alimentarius Commission, shall apply.

A nutraceutical which is not provided in these regulations, shall be manufactured or sold in India only on prior approval of the FSSAI which shall be accompanied by documented history of usage of at least fifteen years in India, or thirty years in the country of origin.

Need for Regulatory Reforms:

In the last few years, there have been tremendous growth of Health Supplements and Nutraceuticals business all over the world. A number of new ingredients / products have been found to be very effective on health related issues. Also, the present level of RDAI of ICMR appears to be insufficient to give desired effect.

NIN - ICMR conducted study to revise the RDAI. Meanwhile, they have submitted a report on Tolerable Upper Limit (TUL) for vitamins and minerals. FSSAI also issued a circular on TUL. However, Section 22(1)(a)(II) of the FSS Act, prohibits the use of more than one RDAI, TUL is of no help unless the FSS Act is suitably amended .

FSSAI also notified 400 botanical ingredients in Schedule IV of the regulations, which can be used as an ingredient in health supplements and nutraceuticals. For approval of any ingredient which is not specified in Schedule IV, application along with fees of Rs 50,000/ plus safety studies and regulatory status to be submitted to the FSSAI. Since some of the ingredients/products do not have documented history of use of 30 years in the country of origin, these are not allowed by the FSSAI. Even if these are available, FSSAI insists clinical trial of these products on Indian population which is time consuming and costly affair for the food business operators.

During the present COVID-19 Pandemic situation, a number of health supplements and nutrition products have been found to be effective immunity booster in overseas countries. But these products are not allowed by the FSSAI as these products have ingredients with higher RDAI. As per existing ICMR guidelines, RDAI for vitamin C is 40mg and zinc is 12 mg whereas most of these immunity booster contain 500/1000 mg vitamin C and 50 mg zinc.

Joint Parliamentary Standing Committee Report:

Department - related Parliamentary Standing Committee on Health and Family Welfare, presented 110th report on "Functioning of Food Safety and Standards Authority of India " on 9th August, 2018 to the Rajya Sabha and Lok Sabha. As former Director, FSSAI, I was an invited member and submitted my suggestions, most of which were considered and included in the report. The committee learnt about Health Supplements and Nutraceuticals regulations of the FSSAI.

The committee recommended that FSSAI should systematically evaluate the performance of the FSS Act, its rules and regulations. Amendments required in the FSS Act were also recommended.

Proposed Amendments of the FSS Act:

Ministry of Health and Family Welfare, Government of India, vide its public notice of September 23, 2020 invited comments and suggestions on the proposed FSS (Amendment) Bill, 2020.

It has been suggested that under Section 22(1)(a)(II) of the FSS Act, "in amounts not exceeding the Recommended Daily Allowance for Indians" to be deleted and replaced with by TUL as now it is officially determined by NIN-ICMR too. All derivatives, salts, chelates, esters and related forms of vitamins and minerals mentioned in Schedule I of the Health Supplements, Nutraceuticals regulations may be used. Methylcobalamin, L- Methylfolate shall be included under vitamins as well as in the respective Schedule I and Schedule VI.

There is an urgent need to amend the regulations, particularly to allow novel food/ingredient which will be manufactured under the Prime Minister's "Make in India" programme. In a rapidly changing world, we should not wait for documented history of usage of at least fifteen years in India, or thirty years in the country of origin. This condition should be deleted.

Conclusion:

Regulatory reforms is a continuous process. Procrastination in granting approval of novel food/ ingredient hampers the economy of the country. Scientific evolution should be encouraged to boost the Health Supplements and Nutraceuticals industry which offers enough scope not only for domestic markets but also export.

About Author:

Dr. Pradip Chakraborty, Former Director, FSSAI.

He did Food Technology and Bio Chemical Engineering from Jadavpur University. He was Director of the Food Safety and Standards Authority of India for three years from 2012 to 2015. He had attended a number of national and international seminar as invited speakers and visited USA, JAPAN and Indonesia. All India Food Processor Association awarded him President Special Award in 2013 for his outstanding contributions to food processing industries.





Mission Challenging But Necessary



Just ten months back nobody in the whole world ever thought that the SURVIVAL instead of GROWTH would become top-most agenda for all the business houses, all the service sector enterprises (such as healthcare, hospitality, travels etc.), industries, corporate, govt., non-govt., MSMEs, Educational Hubs etc. due to completely disruptive attack of invisible enemy i.e. COVID-19, causing pandemic of gigantic order. The leaders and strategists from all these entities all over the world are in complete disarray in this war with Corona! Suddenly and shockingly everything seems to have changed. The whole world has woken up from the deep slumber of stability and sustainability of their organizations, big or small, old or new, public or private, global or local which hardly matters. All of us have to survive and sustain while fighting this unprecedented attack on humanity by this most formidable invader- Covid-19 virus!- By

Mr. Ramesh Sangare



The World Caught Unawares:

Almost all the global experts, news channels, fortune-tellers are bombarding the negative possibilities and predictions about the impact of this war forecasting economic doom resulting into social, economic, political chaotic upheavals around the world. The most powerful and advanced economies have been rendered helpless and debilitated. Developing economies seem to lose the grip on their national wellbeing. Underdeveloped are further whirling down the abyss. More energy is being spent on spreading the gloom and doom, by one and all, from all the continents, with wide spread blame-games in local and global politics. We are all witnessing the massive change in all the aspects of human life all over the world and in India. We have to manage today and tomorrow and days after tomorrow in the already changed world, threatening human race to the core. We have to save lives and at the same time provide livelihoods through services, industrial and business organizations apart from govt. sector and civil society organizations.

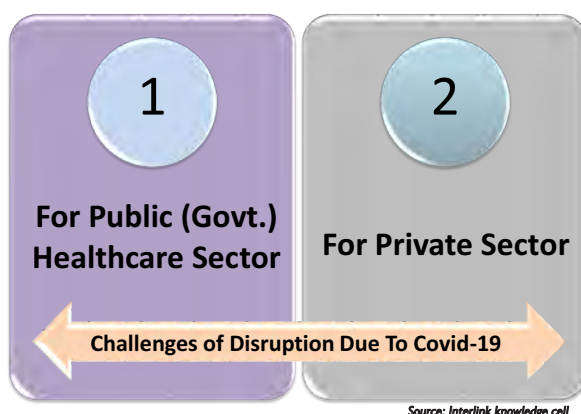
One of the most adversely affected sectors is of course- the healthcare sector, both public and private, with huge challenges, which need to be tackled urgently and relentlessly due to multidimensional impacts caused by this frightening pandemic. Before we go into the strategic thinking and planning of survival and growth of healthcare sector, let us look at the challenges faced by them realistically.

Challenges of Disruption Due to Covid-19:

Both the public and private healthcare sectors are under unprecedented pressure of delivering services of saving lives of millions all over India, with its unique set of challenges, as the most populated democracy in the world.

1. For Public (Govt.) Healthcare Sector:

- For them, it is the matter as usual, except that with most urgent need of larger capacity of beds with ventilators, ICUs, larger nos. of medicos and paramedics and house-keeping and safety- security staff etc.



Source: Interlink knowledge cell

Fig. 1.1: Challenges of Disruption Due To Covid-19

- For the first time several govt authorities such as state and central govts; local self-

govt such as municipal corporation, municipalities, healthcare, food & drugs authorities, commissionerate, PWD, police departments had to come together, which itself is the biggest challenge. It is indeed very difficult to create synergy between these different govt agencies on the ground level, due to political games, bureaucratic hurdles, delays in funds allocations on war footing.

- No confirmed specific treatment available in the form of antiviral drugs and vaccines and inadequate life support system.

I. For Private Sector:

- The urgent need for larger and specific capacity for Corona patients, while keeping other patients safe and secure
- Heavy dependence on empirical and cost-prohibitive treatment and inadequate life-support systems
- The unprecedented exodus of medical staff and para medical staff due to fear and enhanced income opportunities outside
- Drastic reduction of regular general patients in OPD and IPD both
- Drastic reduction in regular revenue coming from multi-specialty facility
- Need for reduction of medico and para-medico staff causing IR, HR and admin problems
- Extreme variations seen in patterns of charging of fees from moderate to very high costs of treatment comparable to hospitality industry, creating huge cry of people, press, electronic media, NGOs, and govt agencies against private hospitals
- Forced govt. emergency services regulations for sparing capacity and services at the prescribed rates for hospitalization services of Corona patients
- And for the last 3 months increased competition from Jumbo Corona Centers ranging from 100 to 800 beds with all emergency facilities, which also attracted the patients and very large no. of doctors and nursing staff from private to this temporary public sector healthcare facilities due to high salaries and incentives offered by these facilities
- Rising cost of existing regular medical and also paramedical staff with enhanced financial incentives
- Continuous reduction in operating profit margins
- Increased interference by govt authorities causing impacts on goodwill of hospitals
- Insecure and unsafe working conditions

These are real economic-financial and administrative impacts on the private sector healthcare establishments with varying degrees of damages depending upon built-in financial and management capabilities of the facilities.

Behavioral Impacts on Healthcare Facilities:

Human race has witnessed and won wars against pandemics, with the recorded history of little more than 500 years successfully. But this pandemic differs from earlier episodes because of some inevitable changes in the modern world such as shrinking of globe with increased global trade, rapid transport, massive people to

people contact of different countries on daily basis, and of course population explosion around the world. As a result of this, healthcare facilities all over the world are under phenomenally high pressure of governance and management, day in and day out. As the second most populated country in the world, Indian healthcare industry is naturally facing extremely critical and turbulent conditions.

All healthcare personnel like doctors, visiting consultants, paramedics, housekeeping, administration, safety and security staff are facing fundamental fears of human mind such as fear of death, fear of invalidity, fear of poverty, fear of severe ill-health, fear of physical attacks from relatives and friends of patients which cannot be underestimated and taken lightly. Massive tangible and intangible mental depression has already set in most of the stakeholders in smaller or greater degrees. Getting best out of them relentlessly is huge task and it needs very strong, resilient, empathetic, reassuring, pace-setting, result-oriented leadership not only at the operating level but the leadership at all the levels from the top to bottom!

What Needs to be Done, Strategically?

It is huge organizational leadership challenge at all the levels. James Mouton says that leadership is dynamic function with no holidays and respite. He gave formula for leadership:

$$L = f(I, F \text{ and } S),$$

Meaning, L= Leadership, f= function of I=leader himself, F=his followers and S= Situation

There are 3 variables i.e. leader himself, his followers and the highly uncertain situation on which we have hardly any control at present, which makes leadership high and low in its delivery of performance. Yet we have been watching the leadership works wonders even in such a turmoil. How?

We can still conquer this war and take the organization to survival, stability and sustainability provided the following four most fundamental skillsets are used with decisiveness and resilience throughout the cross section of the organization. And these basic skills are:

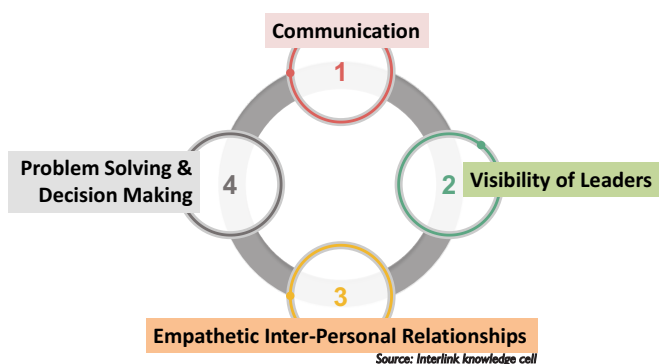


Fig. 1.2: Fundamental Skillsets

1. Communication: Lifeline of an organization in practice to be done seamlessly, constantly (in 26/11 terrorist attack on Taj Hotel (HR) Management spoke with one to one continuously with over 653 families whose family members were trapped, killed, injured and saved)

2. Visibility of Leaders: Physical or digital visibility of leaders on the job and at least daily one visible communication from top leader with workforce is great motivator and morale builder in such emergency situations

3. Empathetic Inter-Personal Relationships: staff is more worried about their families in such life-threatening situations wherein one is working. The leaders have to assure them that organization would safeguard their life and interests. Policies such as these would have to be framed and communicated to the staff without losing time

4. Problem Solving & Decision Making: more practical flexi-approach to problems solving and decision making with less bureaucratic hurdles of usual management practices coupled with calculated risk-taking as the modifier, challenger, synthesizer and innovator (if possible), will augment the confidence of the people working on ground level

PRO's Role:

One more vital function is extremely essential from behavioral management point of view i.e. the role of Public Relations Officer- who must connect and communicate effectively, courageously and realistically with all the external elements such as relatives of patients, press, govt. agencies which really matter most to avoid misunderstanding and its negative impacts. We have come across many cases of external communication failures with external factors such as this.

HR & Finance Synergy:

Besides this viable, logical finance management has to be taken care in order to meet the enhanced expenditure of staff, increased salaries, Covid-incentives, other emergency interventions. We have seen proper dialogue with staff unions conveying them about the present lose-lose situation (as there is no win-lose condition any more) has helped many organizations in getting cooperation resulting into effective coordination in all these emergencies. HR, finance and admin have very crucial role to play in keeping entire working staff in life threatening working conditions, highly motivated with assertive communication skills and emotional intelligence. We must always remember that nearly 1.5 million years back man found the fire and since then he had been growing, fighting all kinds of wars, as the urge to live and grow is most fundamental for survival. Man-made wars for power, land and religions, natural calamities like famines, floods, fires, earthquakes ideological cold wars, trade wars, all of these, human race has faced, fought and won.

There is definite light at the end of tunnel. India would be great winner in this war and would emerge as the power to reckon with. The Indian medical fraternity is known for its grit and guts with excellent record of superb expertise of alleviating

human misery world over, with their dedication with obvious human overtones. It would not be a matter of surprise if India would emerge as the most dependable healthcare-tourism hub globally in the near future. Wait and Watch!

About Author:

Mr. Ramesh Sangare, is a President & CEO of HRDC Group, Nagpur, Pune & Hyderabad (India). He has been nominated as Member of Editorial Board of NIPM (National Institute of Personnel Management) Kolkota Publications- "NIPM Newsletter" and "Personnel Today" for 2014-16. He has been Mentor and Advisor to NIPM Nagpur Chapter, Life Member of NIPM & Life Member of NHRDN. He is one of the Founder Members of Vidarbha Management Association (VMA).

He has conducted all India Webinar on 14th June 20 as the Moderator for Times of India Group and NIPM addressing Industrial Sector on the Topic- COVID-19- Impacts and Opportunities attended by around 350 participants all over India.





Transforming Execution Culture



*Perhaps never before in the history of mankind has the world faced a VUCA (Volatility, Uncertainty, Complexity and Ambiguity) event like it has faced during the pandemic of the coronavirus. In our wildest nightmares we did not envisage that someday our fast paced world would come to a sudden standstill. The effects of the pandemic will be felt for years to come with its devastation of economies and industries, stress on healthcare systems all over the world, loss of jobs and livelihoods, loss of lives and strain on mental health. From all evidence it appears that we will experience wave after wave of outbreaks and until there is a vaccine or a cure we will be vulnerable. - By **Dr. Ruth D'Souza**.*



Every business has had to scramble to cope with this sudden disruption of activity. For those who were already ahead of the curve and were digitally empowered, it was easier. For the rest it was a struggle to catch up and figure out on the fly how they should move ahead. The challenges were multiple. Rethinking how to meet customers, ensuring products are available, meeting production schedules, running marketing campaigns, while caring for the health and safety of their people. 2020 was the year where survival, flexibility and the agility to change were critical requirements.

The healthcare and pharmaceutical Industry in particular has been at the forefront of the response to Covid. From ensuring availability of medicines especially life-saving ones to immediately rolling out crucial research in search of a vaccine while trying to maintain the day to day normalcy of operations, the pharmaceutical industry has done a fantastic job in responding to the crisis.

Being an industry, which depends on human capital, the healthcare and pharmaceutical business faced challenges in strategy execution even in pre-Covid times. Obviously, these were aggravated due to the constantly changing situation, the hard lockdowns, the lack of knowledge of the virus and the fear psychosis of contracting a highly contagious and deadly disease of which not much was known. One thing is clear, we are not going back to business as usual. The changes are here to stay. So, what will be needed of us to ensure we support our people to perform? How do we address the challenges of this new context?

Key Execution Challenges:

While there are multiple ways to define execution, in the final analysis it is the sum total of the hundreds of decisions that employees have to take at the frontline on a day to day today basis, while performing their roles. Our reality today is that with the dynamic of business changing on multiple levels, we will have to identify and address these issues so that we enable goal achievement and performance.

1. Meeting Customers: Relationships define human behaviour. The pharmaceutical industry depends a great deal on the customer relationships developed by regular meetings and face to face follow up. Now the buzz word is 'social distancing' with many customers limiting number of visits, refusing meetings and to some extent moving to a virtual platform. While the medical representative will always remain a key factor of pharmaceutical selling, we need to equip sales and marketing teams to be able to connect with the same quality albeit with a mix of physical meetings and digital engagement or 'phygital' as has been coined colloquially.

2. Managing Remote Working Teams: Remote working for field force is always a challenge. Remote managing of the field force is an even greater challenge especially since much of the sales management work was done during accompanied working. Field managers and senior managers would work together with front line sales

persons and train, motivate, engage and support them to build relationships with customers in search of the targeted number of prescriptions. With travelling being limited, we have to find ways to empower and equip line managers to manage and monitor their teams and guide them to deliver their numbers while managing their teams remotely.

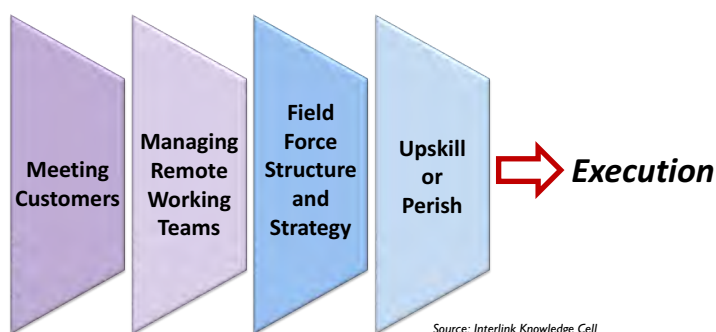


Fig. 1.1: Key Execution Challenges

3. Field Force Structure and Strategy: In view of the commoditisation of brands as well as the constraint to communicate multiple brands to doctors, companies have used divisionalisation as a key strategy for growth. The economics were workable with field force expected to meet an average of 12 doctors and 6 chemists within a tight customer list, considering travelling and waiting times. Now, with the limitations on physical meetings and customer communication moving online, companies will need to rethink their coverage strategy. The way that we target doctors, meet them, service them and build relationships will undergo a change.

4. Upskill or Perish: It goes without saying that change compels upgrading our skills lest we become obsolete. The new context necessitates that each of us acquire new skills to remain relevant and competent. Some of the new skills we will need to add to ourselves and to our teams include:

- i. Omnichannel marketing/ integrated 'Phygital' marketing
- ii. Change management - agility, flexibility, speed and adaptability
- iii. Creativity and innovation
- iv. Critical thinking and data driven decision making
- v. Remote working and management
- vi. The discipline of execution
- vii. Leadership and motivation of teams
- viii. Building resilience
- ix. Emotional intelligence
- x. Technical skills to leverage the digital platform

While CEO's debate whether to conserve resources or spend on development, the

argument has to be for 'investing' on people and equipping them to navigate this new territory successfully for in their success lies the organisations performance.

Conclusion:

In every crisis lies an opportunity. Much as we would like to go back to the familiar space of the old normal, we must accept that change is here to stay. Disruption brings in its wake something new. We need to prepare for how are we going to ride the change and figure out how best we can improve the quality of our execution, build the confidence and morale of our people, and thereby deliver results.

Key areas to focus on include upskilling our teams and reskilling teams, developing competencies of our managerial teams for remote supervision and moving our marketing to a combination of digital and physical.

About Author:

Dr Ruth D'Souza, is the Managing Director of InteGREAT People and is a much sought after Corporate performance trainer for senior leadership teams. She is known for her practical, implementation oriented approach and her ability to inspire and bring about a transformation in the performance of teams. Over the last 30 years, she has successfully led Strategy execution and Leadership Development projects for leading corporations in India and South East Asia. ruth.dsouza@integreatpeople.com



Judge Not.. It Is Productive



*Head count freeze, long approval time from Global HQ, union issues, ever increasing cost of manpower, managing attrition, induction training, rural expansion, less resources --- are just some of the best reasons to explore a tested and trusted tactics 'Contract Selling' also often termed as contractual sales force, CSO, franchise, outsourcing etc. By **Mr. Saikat Mukhopadhyay***



'Contract Selling' - the very terminology itself loudly communicates that it is not about outsourcing of payroll or hiring few contractual staff to promote a set of products in the given geographies. The model has much more to offer to the client organization and can create a real long-lasting confluence of performance, satisfaction, and ease of operation. The basic difference of contractual sales model vis-v-vis model is "accountability of achieving mutually agreed sales / growth targets" – the most desired outcome an organization expects, from any kind of outsourcing.

Globally, this is a recognized and effective tactic for efficiently managing sales functions and driving different growth strategies. Mostly upcoming research driven organizations completely outsource / contract their sales function, so that they can focus on their core competency of R&D or manufacturing excellence. On the other hand, large organizations often effectively use contractual sales teams for driving their growth strategies and product life cycle management strategies like geographical expansions, orphan brand management and various other MDAs (Market Development Activities). A general SWOT analysis of contractual sales model is given below, however this is more apt for Contract Sales Organization driven models of contractual sales and may slightly vary in other models of outsourcing like franchising or brand outsourcing.

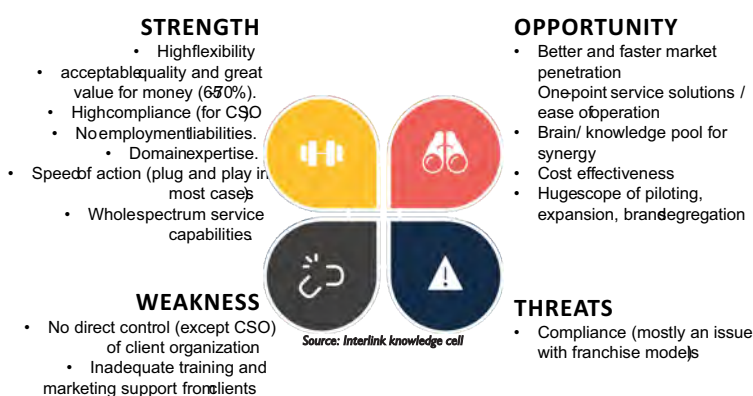


Fig. 1.1: SWOT Analysis of Contractual Sales Model

Benefits of Contractual Selling:

Despite many pros and cons, contract selling offers multiple benefits to the client organization, the most prominent of which are:

1. Accountability of delivering promised result
2. Comparable quality (in CSO) at a better value for money (better RoI)
3. High flexibility and zero employment liabilities
4. Brain pool to add values (especially in case of CSOs)
5. Plug and play models help in rapid expansion and headache free execution
6. Flexibility of piloting new marketing ideas and customization of such models

7. Professional outsourcing means complete process outsourcing and thus offers end to end solutions to client organizations.

Globally many contract sales organizations offer a whole spectrum of services individually or as a group, which include

- 1. Licensing and product registration
- 2. Master distribution n warehousing
- 3. Product n sales management
- 4. State of the art tracking n CRM solutions
- 5. Separate services for patient care n MDAs
- 6. Recruitment and HR services
- 7. A great network with best of the professionals to offer the best strategic solutions and go to market strategies

Contractual selling is not just outsourcing of payroll and hiring a capable contract sales organization may offer not only result but also great peace of mind. In fact a true contract selling model includes the entire hierarchy like M.R., ABM, RBM and Project Head, supported by a strong MIS system and a capable senior management team. For sure, a few outsourced M.R.s does not represent a proper contract sales model.

Contract Selling Models:

There are multiple models of contractual selling but most common are -

- 1. Franchise model
- 2. Contract Sales and Marketing Organizations
- 3. Outsourcing of EMR (exclusive marketing rights)
- 4. Engaging outsourced sales team through payroll outsourcing (however this is not actual contractual sales model)

Let us compare these major models of contract selling to understand the major differences.

PARAMETER	Franchise Model	Contract Marketing & Sales (CSMO)	EMR	Payroll Outsourcing
Accountability	High	High	Moderate	Low
Control of parent organization	Low	High	Low	High
Promotional Ethics	Moderate	High	High	High
Investment Requirement	Low	Moderate	Low	Moderate
Involvement of client org	Low	low	High	High
Sales process	Moderate	High	High	Moderate
Quality of reporting	Low	High	Low	Moderate

This rating is based on most seen practices and exception to this exist for all above models

In India most common is franchise model basically due to no / less investment. But due to increasing regulations on compliance, codes of promotion and lower quality many professional organizations have switched to or actively considering CSMO or professionally managed Contractual Sales and Marketing Organization, who certainly offers better compliance, higher flexibility, knowledge pool and better quality of people.

Source: Interlink knowledge cell

Fig. I.2: Comparison between Major Contract Selling Models

If we glance through the contract selling landscape in India, we can see many projects which are exceptionally successful and continuing for decades even, on the other hand many projects that were closed within six months of launch. Let us quickly try to understand why some projects were so successful and some died even before blooming. The most important factors for success of contract selling related projects are:

1. Internal buying within client organization and strong SPOC from both client and service provider side
2. Selection of proper outsourcing partner – there must be alignment of project objective
3. Adequate control / mentoring of outsourced partners through a strong client SPOC / lead manager. Mandatory tracking parameters are - a. Payment to field force b. Compliance (PF, ESI, Insurance) c. Allowance structure of field force d. Quality and trainability of sales team e. Documents validation like stock and sales statement, incentive disbursement etc.
4. Adequate product and selling skill training, promo support for best effectiveness
5. Master access to reporting software
6. On time payment to service provider
7. Constructive monthly review on quantitative KPIs and qualitative market responses / feedback

While Selecting Your Contract Sales Partner the Must Checks are:

1. Compliance record (this gives clear idea of their management practices)
2. Geographical presence
3. Experience in contract sales domain
4. Infrastructure of reporting, recruitment, and field sales management
5. Track record / reference
6. Do they really respect confidentiality or flash client's name in websites!
7. Market specialization (metro / specialty / rural etc.)

Where All Contractual Sales / CSMO Can Be Used:

Historically franchise model was used for handling declining / old mass market products but with significant development in quality, professionalism, and capabilities, CSO / CSMO models are used for

1. Launch of new division / organization / product
2. Blitz campaigns
3. Rural marketing / extra urban coverage
4. Coverage of uncovered customers in currently covered markets
5. Medical detailing of FMCG / FMHCG products
6. Catch Them Young campaigns
7. Different MDAs especially involving ISMP / para medical staffs etc.

How to Make Contract Selling Projects Successful?

1. Strong SPOC and handholding
2. Adequate training, promo support and SMART targeting

3. Master access to reporting software
4. Involve contracted sales team also a part of star award or throw one separate award for contractual team
5. Train the Project Head of contract sales partner
6. Have empathy
7. Encourage correct practices

Financial Models of Contract Selling / Sales Force Outsourcing:

1. **Franchise Model:** typically, a % of sales generated is paid to the service provider. It's certainly the low investment model and has great success stories. However compliance, quality of people and ethics / quality of sales are the most common issues.
2. **Contract Marketing and Sales Organization:** Normally cost of sales force is reimbursed with management cost and profit of service provider and a low profit sharing on sales generated also is given, especially for launch of organization. The model involves investment, but compliance, control and quality are mostly better than franchise model. Most successful projects in this model are linked with incentive and penalty linked financial models. Many great projects are successfully executed through this model.
3. **Exclusive Marketing Right:** This is practically similar to franchise model from a financial point of view. However, quality and compliance not an issue here as outsourced products are handled here by regular field force of leading organization. The issue is mainly R&D driven / niche products are outsourced in this model and practically there is no control of after outsourcing the product/s.
4. **DIF model,** this is another heavily practiced model where project cost is calculated and then divided by number of M.R.s and # of avg working day to arrive at a loaded cost / day or DIF RATE. Theoretically this is a great model for ease of calculation and to ensure so called "arms' length distance" but this model has too many buffers to make extra money, which mostly leads to compromised service delivery. Many times, this model is further broken down to cost / call or similar denominators but basically essence remain same and pros and cons as well remain same.

My personal experience says, cost plus model is the best model and can lead to great outcome from such contract sales project with a great concinnity of quality, process and performance.

Only thing we need to remember that even contract sales organization or franchises also need resources, skills and environments, which are absolutely similar to an inhouse sales team and proper facilitation and structuring the outsourcing model pragmatically will give extraordinary results.

Many of us will remember the iconic punch line of Hero Honda “fill it, shut it, forget it” contract selling, if managed properly can echo the same as “select it, mentor it, enjoy it!”

About Author:

Mr. Saikat Mukhopadhyay, Managing Director Nijji Healthcare Pvt Ltd, is a passionate entrepreneur with major areas of expertise in Contract Marketing and Sales Solution, Medical Detailing of FMHCG Brands and Socio Commercial Business Models. He is also a recognized nature and wildlife photographer by passion. An avid learner with continued hunt of qualifications like; PGD Digital Marketing Strategy - Amity ; Professional Course on Digital Marketing from Wharton Online, ECP Entrepreneurship - IIM KASHIPUR and multiple other qualifications from Google. His one of the article is published in APHA on Healthcare in rural India, as a co-author and C.O.P of DAZT Project, FHI 360.





Ready for Meaningful Career?



*Taking strategic decisions based on experience and gut-feeling is thing of the past. Successful business decisions are now based on data-derived information whether they are financial, operational, strategic, and so on. Let's look at what is Data analytics and how it is relevant in Pharma and Healthcare set up in India. - By **Mr Ashish Babtiwale***



“Data scientist: The Sexiest Job of the 21st Century” – Harvard Business Review (HBR)

When business school like Harvard makes such a statement, it is the vision for the future job opportunities. HBR Analytics Services Survey, July 2019 suggest that many organizations are taking important steps toward integrating data and analytics into routine business operations.

Data analytics is a process of collecting, inspecting, cleaning, transforming, and analysing data to generate real-time insights that can help in making crucial decisions faster.

Is It Science or An Art?

Data analytics process is definitely science and can be learnt, practised and developed. But what makes it the art is the human intervention that is needed to understand the problem, define the issue and bring in clarity through right choice of analysis parameters. The domain knowledge plays an important part. The data analytics enables to take raw data, process it and uncover patterns to extract valuable insight ...common parlance used in most boardroomsfor data based decision making (fig 1.1).



Fig 1.1: Steps in Data Analytics

Source: Interlink knowledge cell

Who Can Become A Data Scientist?

Any individual who has ability and inclination to learn and wishes to discipline analytical mind to make the data useful can become a successful data scientist. Data scientist converts the data into actionable insights.

Peter Sandergaard (Gartner Research) quotes - Information (data) is the oil of 21st century & analytics is the combustion engine that will drive businesses.

Data analytics is often viewed as 'engineer's domain'. But, when it comes to domain knowledge, engineers have to rely on domain experts to understand needs and to clarify the intricacies and issues related to specialized fields, may it be finance, healthcare or education.

Role in Healthcare and Pharmaceutical Industry:

In current times of digital influence, the changing landscape of healthcare is creating a huge demand for health data analytics. The major challenges that industry is facing today are increasing regulatory rules & regulations, decreasing research and development (R&D) productivity, pressure on revenues/ profitability growth and

adaptation of digitisation in value chain. Modern and cutting-edge data analytics provide help in improving patient care, raising standard of care and achieving quality parameters at minimised costs. What can bring relief to businesses is hiring people who can build data based strategies, data driven operational efficiencies (cost & time) to be predictably right at the first instance in field of R & D, clinical trials and data management, marketing, sales, HR, logistics and importantly targeting and reaching the right customer productively.

Where Does the Opportunity Lies?

Data Science is the future for all industries. It's more crucial to healthcare sector as the demand is growing in Indian market as per various reports published. In fact, by 2021 need for more than 20000 data scientists is predicted in various departments including R&D, clinical data management, manufacturing science, sales-marketing & logistics. IBM predicted that the demand for data scientists will increase by 28% by 2020. It is stated that there will be demand for ~50,000+ Data Scientists in India in 2020-2021, second to the United States.

The future of the pharmaceutical and healthcare industry lies in overcoming barriers to innovation through data analytics optimisation. Pharma Industry is moving past the challenge of unstructured data sets and integrating data from multiple sources to begin to work collaboratively with other departments and organisations. The process to create a real world evidence framework for the pharmaceutical research and marketing development through effective data utilisation has already started.

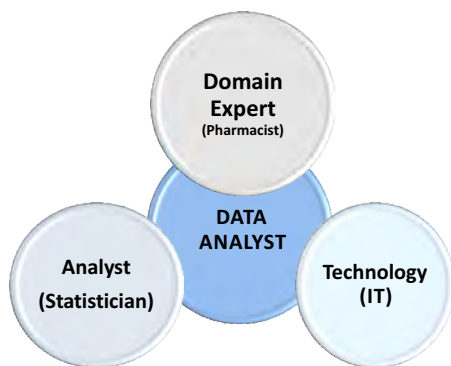


Fig 1.2: Skill Sets Needed for Successful Data Analyst

As of today, few pharma organisations and many allied analytic consulting companies, looking for data scientist, are unable to get candidates with relevant domain knowledge. This is more surprising, when 4,00,000 pharmacists are graduating every year in India and recruiters are not satisfied with merit available when 'Data Scientist' is a need. This is an outcome of limited awareness among pharmacists and healthcare/life-science professionals to identify and exploit the emerging opportunities.

Combining Two Different Skillsets:

Pharmacy domain knowledge & data analytics acumen with technical knowhow can take one to the next pedestal in the career path (fig. 1.2). It will not only be lucrative but will empower one to take decisions to climb up the ladder in the organisation faster because the business world is embracing data scientists who can extract value from the most puzzling data sets.

Interesting to note that, Executives from some high-performing departments report even higher rates of data and analytics use. Mature organisations see improved customer satisfaction and business performance as the result of their analytic investments (fig. 1.3).

ANALYTICS MATURITY IS CRUCIAL TO ACHIEVE BUSINESS OUTCOMES

Mature organizations see improved customer satisfaction and business performance as a result of their analytics investments

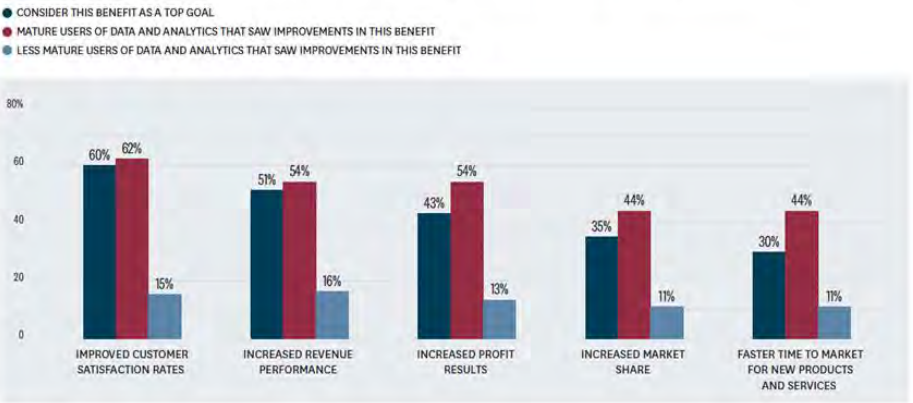


Fig. 1.3: Investment in Analytics Yielding Great Results

There is an emerging need for pharmacists and science graduates to get trained in the area of data analysis and mastering the agile, fast, interactive software to maximize data values and support decision making. Combining this with the domain knowledge, pharmacists can take full advantage of tools and techniques that are capable of handling unleveraged and insightful results in a simple, easy-to-interpret way.

Business intelligence delivered by data scientist in healthcare permits organizations to build a reputation around the patient, clinical care, and also drive collaboration through all departments. Healthcare data volume is expected to grow dramatically in hospitals in the years ahead and also thru patients apps etc; it is vitally important for healthcare organisations to acquire the available tools, infrastructure, and techniques to leverage data science effectively.

What Should You Learn?

Application of customer friendly software available in the area of statistics (for data interpretation), languages (Python), dashboarding and visualisation tools (Power Bi

& Tableau) will make you ready for the job. The upcoming technologies like Predictive Analytics, Artificial Intelligence, and Machine Learning will help revolutionise healthcare standards and impact our lives to a great extent.

The career in data analytics is very lucrative. Pharmacists and healthcare/life science professionals who want to take their career to next level can enrol to various online certification programmes in data analytics. Recruiters are always in search of skilled people, especially, in the domain area of healthcare industry. The knowledge and certification can help you gain an edge over others.

It's time for all of us to get digitized and be prepared for miracles going to happen in the coming years

About Author:

Mr Ashish Babtiwale, with 30 years of experience in field of pharma healthcare, is Managing Director of Navigo Analytix, the organisation assisting organisations in converting data into actionable insights for revenue growth & operational excellence.

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Great Expectations-API



*The changing dynamics, evolving regulatory and compliance landscape and initiatives by drug makers are propelling the incorporation of new Active Pharmaceutical ingredients (APIs). This is expanding scope of the revenue generation in the API market. In recent years, sizable growth opportunities have come from the demand for APIs resulted in well-featured roadmap for pharmaceutical business in various countries. Many dominating countries have gained their identity as 'Pharmaceutical Hub'. However, many are still testing their efforts toward this larger segment of market. Southeast Asia is one of those regions. This article sketches the current scenario and revamping strategies employed for profitable API Business in South-east Asian countries. -By **Ms. Mansi Jamsudkar***



Current scenario of API market in Southeast Asia:

Over-dependency on imported ingredients is one of the common issues faced by many countries when it comes to API manufacturing. Extremely small number of manufacturers possess the capability of manufacturing APIs in Southeast Asia. According to Thailand's Food and Drug Administration (FDA Thailand), there are 142 domestic pharmaceutical manufacturers accredited with GMP standards, out of them only 5% are capable of producing APIs. This clearly indicates their heavy reliance on imported ingredients. The situation is very similar in both Indonesia and Malaysia, where finished production of generics is supported by imported APIs. Southeast Asian companies sourced the majority of their API requirements majorly from China (60%) and India (47%). In Vietnam, over 90% of pharma ingredients are imported, and half of these are from China. Local economies are struggling to compete with the lower cost of the large regional manufacturers in China and India. Currency fluctuation and supply shortage resulted in increased prices of raw materials in past few years. Price controls across the region prevent increased costs being passed onto patients. Thus, putting pressure on profit margins.

Talking about regulatory alignments, there are still some parts in Southeast Asia whose exporting potential is hidden due to regulatory incapability. Facilities accreditation with either EU-GMP standards or standards of the Pharmaceutical Inspection Co-operation Scheme (PIC/S-GMP) is the basic requirement for countries in Europe and North America. In the case of Vietnam, only 17 facilities have obtained EU-GMP or PIC/S-GMP standards, compared to 222 facilities with the lower-level WHO-GMP standards. This not only affect the export potential but also prevents sales access to domestic hospitals.

Although there are many hurdles in the path, Southeast Asia is still making newer efforts to be the leading Pharma hub. In the recent years, government has started taking wise decisions toward the betterment of overall economy, giving immense importance to Pharma industry. In my opinion, strategies employed by Southeast Asian government and domestic pharma organizations in the field of API business might fetch the desired outcomes in near future.

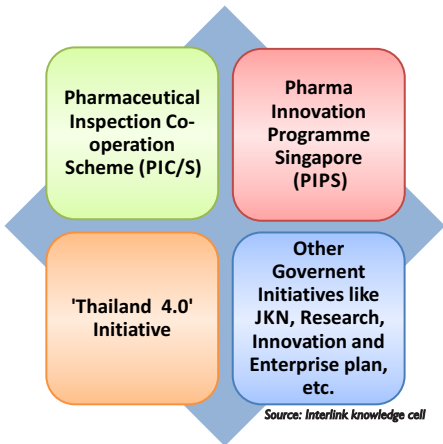


Fig. 1.1: SEASIAN Government Schemes

Following are some government policies which are positively propelling economical and reputational growth in Southeast Asian countries.

Growth Stimulating policies adopted by Southeast Asian government in API Business:

Pharmaceutical Inspection Co-operation Scheme (PIC/S):

It's a cooperative arrangement between regulatory authorities in the field of GMP for medicinal products for human and veterinary use. The US-FDA considers PIC/S to be a global leader in helping to ensure the quality of drugs. It represents the best way to avoid duplication of efforts and to allocate resources based on risk. An ultimate goal of this scheme is to harmonise inspection procedures across the globe by developing common GMP standards, providing training opportunities to inspectors, and facilitating co-operation between both regional and international organisations. In Southeast Asia; Singapore, Malaysia, Indonesia and Thailand have already joined the scheme while Philippines and Vietnam have both shown good interest in completing the process of applying. This scheme will lead to reduced duplicate GMP inspection. So even if many generics manufacturers might face increased costs as facilities are upgraded to meet the higher standards, the outcomes would be profitable and favourable in terms of export. In spite of cheaper alternative available from China and India, the Thai export is gaining identity amongst neighbours such as Cambodia, Laos, Myanmar and Vietnam. Isn't it a favourable outcome of PIC/S?

This harmonization of regulatory standards may provide significant new sales avenues and high growth in exports can be anticipated to Australia, New Zealand, Europe and even North America. Many regional and international companies have greater confidence in Thai manufacturing after it joined PIC/S in 2016. Enhanced reputation and higher standards have allowed the small manufacturers to become globally competitive and ready to export. Some regional industry experts believe that tighter regulations and cost restraints are leading to lower profit margins. Contrary to this, most of the expertise believe that the initiative by government to control drug prices and increase the availability of low-cost generic medicine will lead to increased investment in domestic manufacturing capabilities.

Pharma Innovation Programme Singapore (PIPS):

This is a manufacturing initiative designed to boost the competitiveness of research companies in Singapore's public sector by supplying them with the expertise from big pharma players. The programme is helping to develop continuous manufacturing for API production, as well as implementing biocatalysis technologies for more sustainable production of complex and valuable chemicals. Agency for Science, Technology and Research, the National University of Singapore and a number of large pharma companies are in association to launch the PIPS. PIPS consortium will focus on increasing productivity and operational efficiency through technology and data analytics. This will raise the bar for pharma manufacturing,

resulting in more sustainable processes and quicker production of APIs. This will not only boost the domestic pharma market but also will improve the internationalization of Southeast Asian API market. Although Singapore already has a well-developed, mature pharmaceutical market with a reputation for high quality and even innovative manufacturing services, initiative like PIPS is emerging as double-strength growth booster in Pharma field.

According to CPhI South East Asia Report, notable investments in the market from big pharma in previous years include GSK's \$130m continuous manufacturing facility, as well as WuXi Biologic's and Novartis' biologics plants, with the companies investing \$80m and \$500m respectively. Singapore's biomedical manufacturing output has increased subsequently by nearly 10% in the first half of 2019 compared to the corresponding half of 2018. This has further established its reputation as a prosperous biomedical manufacturing hub.

Thailand 4.0:

Thai government is looking to make Thailand a leading pharma destination in the region, 'Thailand 4.0' is an initiative taken by Thai government to positively shift country's reputation in the field of API business . While not solely focused on pharma manufacturing, this initiative has already seen state-of-the-art facilities set up at the Thailand Science Park with clean rooms, sensitive labs and high-performance technologies. An aging population and rising rates of non-communicable diseases are driving growth in Thailand's medical industry, particularly in pharmaceuticals and medical devices. According to an IQVIA report the Thai pharmaceutical market is forecast to grow at a CAGR of 3.7% ($\pm 1.5\%$) between 2017 and 2022, reaching Bt178.1 billion by 2022 (circa \$6million). Removal of mandatory purchasing of generics through the Government Pharmaceutical Organization (GPO) might result in accelerated internationalization of Thai pharma. This has further helped the market to become 'more competitive' and will enable the market to set its own prices. Ultimately, greater opportunities for imports could be generated.

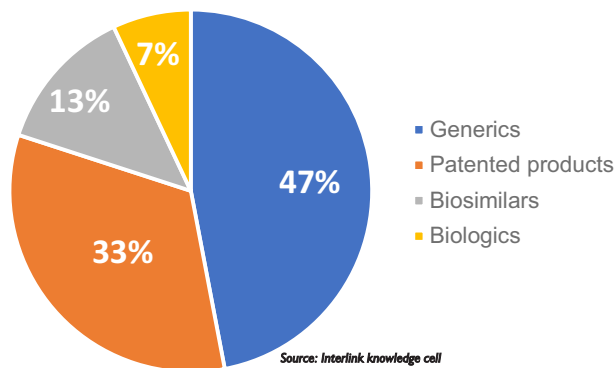


Fig. 1.2: Product classes having the best growth opportunities in the SEA region

Other Driving Forces in Southeast Asian API Business

Most recently, government committed to investing \$2.4bn to improve manufacturing and engineering in pharma as part of a 2020 'Research, Innovation and Enterprise' plan. In Indonesia, the pharmaceutical industry is expected to see increased revenues due to the introduction of the 'Jaminan Kesehatan Nasional' (JKN) - a new Universal Health Care Scheme. The novel anti-malaria drug P218 has been co-developed by Thailand's BIOTEC research centre. This might result in miraculous gain in budding pharmaceutical market of Southeast Asia. IMS Health forecasts that the Philippino market will see 4.5% annual growth over the next few years. The Malaysian Cabinet aims to reduce cost of drugs for consumers. These price controls will cap trade margins for drugs in the country, which will have a cascade effect on all players in the Malaysian pharmaceutical supply chain.

Generics (47%) and patented small molecule drugs (33%) are considered as fastest growing segments in Southeast Asia. However, Biologics and biosimilars (with the exception of Singapore) are not currently seen as promising growth areas. majority of domestic and regional pharma companies have expertise in solid dose formulations as well as newer emerging export markets for cheaper and branded generics. This may offer the fastest returns. In Philippines new laws have made it mandatory for public hospitals to provide generic drugs. Physicians who previously always opted to prescribe more expensive, branded alternatives are slowly beginning to endorse the prescription of generics to patients. The rise in demand for high-quality generics is opening up a fantastic opportunity for both domestic and foreign players. The country is also well set with its manufacturing base, with 14 of the world's top 20 pharma companies owning manufacturing facilities in the Philippines.

Looking at all this, Southeast Asian region might turn out to be next big destination for Indian pharma too. The growing patient pool, ageing population and advanced healthcare systems all make the region an attractive destination for newer drugs as well as for higher investments. Region's international reputation is improving quickly, and increased opportunities are opening up. In my opinion, Government policies and industry level efforts employed are swapping the image of Southeast Asian API market in a positive way. If this works in the same way how it is working now, tomorrow, it would be worth to count Southeast Asia in the list of countries who are dominating this API Business today. Till then, lets appreciate the pure efforts taken by these countries to stay in this rat race to continue maintain their identities.

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Pain Prescription



*Chronic pain is associated with conditions such as arthritis, fibromyalgia, sciatica, and diabetic neuropathy. Chronic pain affects about 100 million people in the United States every day. About 50% of these consumers are not satisfied with current treatments. Especially in today's pandemic ravaged times, managing chronic pain would be a struggle as seeking appointments with pain specialist doctors, physical therapists, acupuncturists etc. becomes difficult. However, patients can go for self-care plan by using FDA cleared devices. Added benefits are that these devices are drug free and hence free from side effects. Discussed below are popular devices used for pain-relieving therapy. - By **Ms. Akanksha Kudalkar**.*



TENS (Transcutaneous Electrical Nerve Stimulation)/Electrotherapy Devices:

Transcutaneous electrical nerve stimulation (TENS) and microcurrent nerve stimulation (MENS) devices use low-voltage electrical current which interferes with nerves' transmittal of pain signals to the brain and hence provide pain relief. These are small electrodes that often work with your smartphone which ensures you are in control of your session's time and intensity. It acts through electrical stimulation. It is theorized that electrical stimulation causes the body to release endorphins, which are natural pain relievers. This helps in healing damaged tissue. TENS could be effective against cyclical pain patterns that are unrelated to physical activity. MENS devices use less amperage.

Cranio-electro-therapy stimulation (CES) of the trigeminal nerve contributes to the alleviation of head and facial pains. It can be an alternative to medication particularly in the treatment of depression, anxiety and insomnia.

TENS units are easy to procure, budget friendly with decades of proven effectiveness and safety. One can perform their daily activities while using them.

Product	Since	Treatment	Price
ALPHA-STIM-M	1981	Joint and muscle pain, anxiety, depression, and insomnia	\$1,195
CEFALYDUAL	2017	migraine attack	\$499
HEALTHMATE TENS Units and Muscle Stimulators	FOREVER 2010	Joint and muscle pain	\$24.99 (for 2019 models) to \$400 (for the 2020 touch screen unit)
iTENS	2016	Muscle, nerve, abdominal, and joint pain	\$79.99
QUELL	2016	Chronic leg, foot, and knee pain	\$249

Fig.1.1 Products Available in Market

Light Therapy Devices:

Light therapy is also known as phototherapy. It uses light energy of specific frequencies and intensities to relieve pain. The types of light used in these devices are - light-emitting diodes (LEDs), infrared (IR), and low-level laser therapy (LLLT) which is also known as cold laser therapy. It relieves pain, reduces inflammation and promotes healing and circulation. LED light therapy helps release nitric oxide from cells that promotes healing on a cellular level, as opposed to just interfering with pain signals sent to the brain as TENS devices do.

Some light therapy devices incorporate radiofrequency (such as the Solio Alpha Plus), using a combination of energy sources. The radiofrequency energy

penetrates the muscles and joints and increases blood circulation thereby treating the source of pain, LLLT treats muscle spasms; while IR and red spectrum treat pain and stiffness.

Medical grade phototherapy devices effectively treat clinical conditions such as osteoarthritis, fibromyalgia, and neuropathic pain such as diabetic neuropathy. The treatments are easy to adopt and the devices are easy to store. Following are a few examples:

Product	Since	Treatment	Price
PAINAWAYLASER	2013	Back pain, muscle spasms, arthritis pain, elbow pain, muscle strain	\$2,995
SOLIOALPHAPLUS	2019	Joint and muscle pain	\$559

Fig. 1.2: Treatments and Prices

Vibration and Percussion Technology Devices:

Whole body vibration (WBV) is gaining popularity in the fitness domain as it reduces muscle pain and increases blood flow. Devices for home use provide vibration therapy to the site of pain. This therapy relieves muscle tensions and enhances speed of tissue recovery.

Product	Since	Treatment	Price
VIBRACOOl	2017	Joint and muscle pain, tendonitis, carpal tunnel, headache	\$89.95
Oska Pulse	2016	Muscle or tissue pain	\$399

Fig. 1.3: Vibration and Percussion Technology Devices

Product	Since	Treatment	Price
NORMATECPULSE2.0	2018	Muscle soreness, swelling issues such as lymphedema or swelling in legs	\$2,195 (full body model), \$1,595 (legs and hips model), \$1,295 (legs only)

Fig. 1.4: Compression Devices

Compression Devices:

These are Vaso-pneumatic devices like these which apply compression to the

arms and legs. These devices are used to treat conditions that cause extracellular swelling. They are heftier to use and store and are expensive.

Heat Therapy Devices:

Heat therapy acts by relaxing muscles thereby reducing pain and stiffness in joints. Applying heat also enhances the flow of blood and nutrients in the body. The moist heat packs generate moist heat that has better penetration than the dry heat given off by electric devices (eg. blankets/pads). For an oxygen starved muscle, heat application increases perfusion and healing. However, it must be used carefully over the joints that are injured or have arthritis. Sometimes, medical grade heat may cause deep tissue heating and the tissue may burn.

Product	Since	Treatment	Price
AVACEN100	2014	Arthritis, muscle and joint pain, muscle spasms, stiffness, minor strains and sprains, and muscle relaxation	\$3,995

Fig. 1.5: Heat Therapy Devices

Drivers of Pain Management Devices Market:

There are two major factors that drive the sales of pain management devices. First is the growing demand for wearable devices and gadgets. These devices will no longer be a novelty but would rather be mainstream. There will be convergence of multiple technologies into a single device. Newer devices manufactured are more user-friendly, portable, lightweight and comfortable. Second, the lifespan of people around the world is increasing. This translates to an increased incidence of pain. Additionally, pain medication is associated with long term side effects. There is risk of dependency also. Hence, pain management devices are sought after as non-drug alternatives. They are particularly popular among those consumers who want to treat arthritis, joint pain, back pain and at the same time limit the amount of medication taken.

Challenges:

Pain management devices are significantly costlier compared to OTC products. At-home TENS devices are priced five to six times higher than OTC counterparts. Patients who suffer from minor periodic pain are unlikely to invest in pain management devices. For example: Sanofi's tube of Icy Hot cream is sold for an average retail price of \$5 while the Icy Hot TENS device is sold for an average retail price of \$30. A bottle of Bayer's Aleve is sold at an average retail price of \$10 while the Aleve TENS device is sold at an average price of \$50.

At this nascent stage of this market, patients are likely to be confused about how the product works or may doubt their effectiveness. Patients will only spend on pain management devices when they see the value in their efficacy.

Distribution and Business Model:

The direct sales channel such as Amazon or the company's website is the best way to reach the consumers. It has shown the fastest growth among all retail channels at 15.5%. However, once the consumers are familiarized with the product after using it, the sales through mass merchandisers such as Walmart and drug stores will also increase.

Most of the revenues in the pain management device market come from repeat purchases of refill items such as refill pads of TENS and not the device itself.

Conclusion:

The pain management device market is expected to grow at a CAGR 12% through 2021 due to wide spread retail distribution and increased consumer demand. The aging population will facilitate the healthy growth of this industry. OTC products and various pain management devices will co-exist with both segments appealing to a variety of pain management needs. Leading OTC players such as Pfizer and GSK could enter the pain management devices segment.

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Ms. Akanksha Kudalkar, She has over one and a half years of experience as a healthcare analyst and has executed multi-country projects. Her work areas include primary (qualitative/ quantitative) and secondary research, market intelligence, brand perception analysis, value segmentation, new product concept testing, conjoint analysis, multi-country tracker studies, market entry, pricing research, brand positioning and market opportunity assessment. She brings on board the knowledge of both core pharmaceutical industry as well as the market research and consulting industries. She holds a Masters Degree in Pharmacy (specializing in Pharmaceutics) from BITS – Pilani.





Stories Build Brand



We all love stories. They are an intrinsic part of all cultures. They create experiences for the listener and enter the hippocampus, located in the brain's temporal lobe, where episodic memories are formed and indexed for later access. Well-told stories stay with us forever. If they are created for customers, they instantly connect and stay with customers for a very long time. -

By Ms. Gauri Chowdhury



“How many of you remember the binomial theorem from mathematics?” I asked the august gathering of senior scientists, entrepreneurs, CEOs and senior managers from R&D teams at the training session. A couple of hesitant hands went up, but the majority remained silent. The audience comprised of the brightest of the minds of the industry. I had no doubt about their intelligence and capabilities. I was not testing their knowledge but was making a point that was very critical to this part of the brand-building part of the session.

“Okay, doesn't matter,” I said, “How many of you remember the VSPER theory from chemistry?” The audience was puzzled by the question and its relevance in brand building class. “We are here to learn how to convert innovations into successful brands and not to answer some 12th standard exam questions; we wrote that exam at least 20 years back,” I heard some of them whisper.

“Well, now the last question,” I said, ignoring the low whispers. “How many of you remember the story of a thirsty crow?” The transition happened. All the hand went up.

Wow, everyone knew the story of the thirsty crow.

The question is, how could the august audience of scientists and entrepreneurs remember a story from early childhood but forgot the scientific theorems that they had learned in their 12th std. The answer is simple. The human mind remembers stories far better and longer than the facts and figures.

A creator of ideas and an excellent storyteller, Steve Jobs famously said, “I don't charge my customers for my products. I charge them for the experiences.” No wonder all the innovations at the Apple inc. proved to be the most successful ones.

Many innovators in the industry are good at the science of innovation, but unfortunately, they lack the ability to convert successful innovations into commercially successful brands. So what is the way around it? How can innovation catch the attention of the customers? What will make it appealing to them? What will make those innovations into a formidable brand?

Well, while there are many aspects to building a successful brand, one of the important aspects is being able to create a story around the innovation that touches the hearts of the customers.

Stories Bring Success:

There are lot of benefits associated with innovation stories.

- Stories instantly connect with the listener: If your listener is a customer, user or a fund provider, stories help you connect instantly with them
- Stories aid recall: Stories stay with humans. They help in the recall. Today when 100s of messages bombard the customers every minute. The stories help break

the clutter and create lasting impressions.

- Stories bring higher ROIs: Brands based on innovations when are sold on facts and figures tend to draw higher efforts, time and money to establish. But stories move faster across the customer segments.

So who do you tell stories to? You tell stories to anyone and everyone to whom you are selling your ideas or innovations. They might be the customers for whom the innovation is created, or they might be the investors who will fund your ideas, or they might be your bosses who need to give the nod to your project. So, technically anyone who needs to hear your idea needs to listen to the story behind the idea.

But I Can't Tell a Story:

Above is the most common expression I hear. In my general observation, people from technical fields often have inhibitions when it comes to storytelling.

Some feel that they can't tell a story. They think it is an inborn trait that they don't have. Fortunately, that is not true. Everyone who knows how to speak knows how to tell a story. We all tell stories to our family, friends and colleagues, be it at the dinner table, office canteen, or friends' get together. Besides, storytelling is a skill that can definitely be learned.

Some say, "I can't tell stories because my industry is different. It is too technical and complex." In fact, if you are in a complex technical field, it is all the more important you have stories about your company, its inventions and uniqueness. In a world filled with technicalities, stories break through the clutter to straight reach its audience's hearts.

The other inhibition is, "Who has the time for stories? My boss always wants me to come to the point quickly." This argument arises from the myth that stories are long. Haven't we all heard the one-line stories? So, stories need not be lengthy and time-consuming. They can be apt and quick. Stories appeal to people and quickly cut the clutter to reach their hearts. Audiences invariably give more time to storytellers if the stories are fascinating. So the audience not having time is the least of a problem.

How Do We Create Stories?

The first step in creating stories is to empathize with the people for whom the innovation might work. Who are these people? What are their problems? How are they currently solving those problems? What are their needs and wants in general and in specific to the problem at hand? What are their dreams and aspirations? How is innovation going to help them solve these problems?

Everyone in the business of innovation must stay in touch with people for whom innovations might work. Getting into their shoes and looking at the world from their eyes help us create stories for them.

Stories have heroes, and the heroes have conflicts. These conflicts are often the source of pain to them. In the course of the story, the conflicts get resolved, and there is a happy ending.

Having understood the user/customer at a practical and emotional level, a story can be built around it. Any good story has four interesting ingredients.

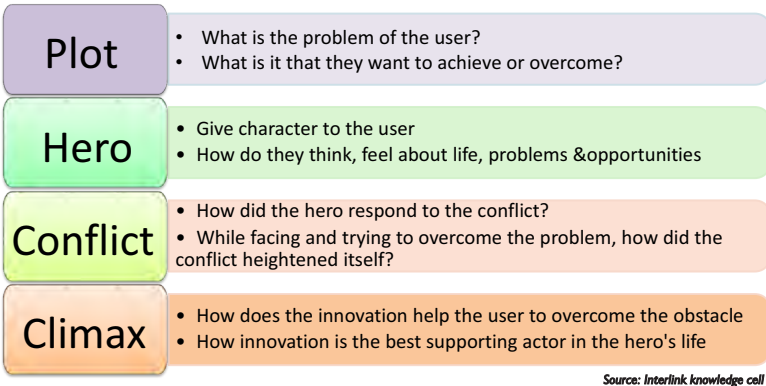


Fig. 1.1: Interesting Ingredients of Story

While working at FCB Ulka's as a part of their global team, I informally got involved in Zofran communication strategy. Zofran is a brand of Ondansetron. Ondansetron is known for its antiemetic properties. Zofran was a great product but went on to become an excellent brand due to its most appealing story-based communication.

Vomiting is the biggest problem associated with chemotherapy. Zofran was indicated for cancer patients on chemotherapy. The team had all the facts and figures about the superior antiemetic properties of ondansetron. But the brand wanted to understand the feelings of doctors, patients and their pain points.

While interviewing the doctors, the team realized that there was a sense of helplessness associated with chemotherapy. Patients often said that the vomiting was far worse than the pain or the fear of death. Doctors were often felt powerless when it came to the side effects of chemo.

Brand Zofran understood this pain of the medical practitioner. The brand was born out of an understanding that it had to partner with the practitioner in making patient's life easy.

Zofran told doctors the story of empowerment. It said, "Doctor with Zofran, you can !!!"

Brand told the stories of victories of patients who could tolerate chemo and successfully went through the therapy. The communication was less about Zofran but more about the feelings of pains and gains of treatment. Zofran had all the clinical and statistical data to answer the questions of the doctors. Still, the opening

of the conversation with physicians was always about patients and their success stories.

There are ample examples of stories across the industries. When the stories are honest, genuine and transparent, they appeal to the people, be them the customers, fund distributors or the corporate bosses.

As Ben Horowitz famously said, "Company without a story is a company without a strategy." Think about it.

About Author:

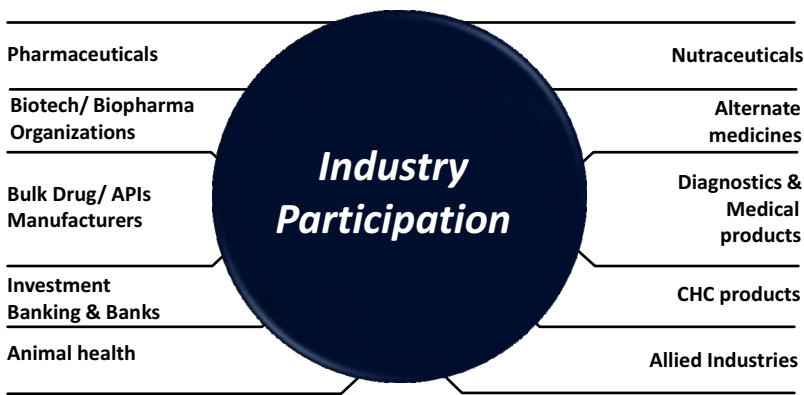
Ms. Gauri Chowdhury, Gauri Chaudhari is a Co-founder of Brand Innerworld, a brand consultancy firm specializing in Healthcare and Pharmaceutical brands. Recently, she has authored a book, The Perfect Pill: 10 steps to Build a Strong Healthcare Brand, published by Sage Publication. The book has been a great success and is declared as 'Hot Release' by Amazon. It trended as the best seller on Amazon in the month of March 20. The book is available in India, USA and UK.

Currently, as a Co-founder of Brand Innerworld Consultancy, Gauri is involved in Brand Audits, Life-cycle management, Insight mining studies for both Indian and Multinational Pharmaceutical brands. She has been mentoring brand managers and marketing managers by providing on- the- job coaching. Brand Innerworld is involved in several exploratory studies to understand physicians' and patients' attitudes and behavior and their impact on pharmaceutical businesses.



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