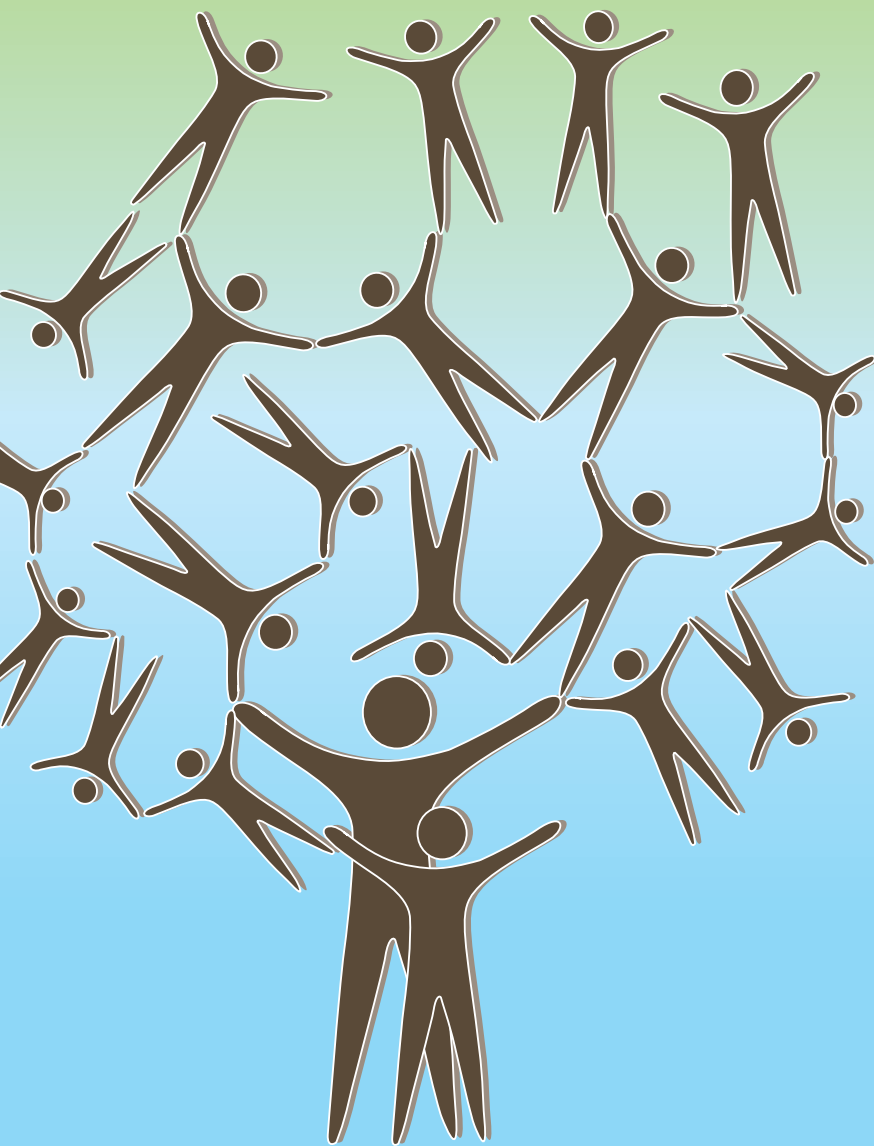


INTERLINK INSIGHT

Perspectives for business performance

SUSTAINABILITY



**With Special
Pharmexcil-
Interlink Report**

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Industry Image

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INTERLINK

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Thinking
Fresh

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FROM THE PUBLISHER'S DESK

Are We Reforming?

Recent visit of Indian Prime Minister Mr. Narendra Modi evoked reformed response and even Jon Stewart, host of a satirical television show, was impressed. He said, "No world leader has drawn that many Americans for anything. Except maybe one of Berlusconi's bunga – bunga parties."! Is our perception reforming?

Can Pharmaceutical industry also undergo intense reformation in perception? Can Pharma Image be reformed?

Despite all the efforts put in by the Pharmaceutical industry to come out with effective and safe products for patients for new diseases, there is still a lack of trust. Can it be improved upon?

We also have cases of extreme violations of ethics involving large business organizations every now and then! So, can ethics be taught?

Can industry also shift its focus from Illness to Wellness and become an agent of Health?

Now the consumers are growing to become more aware of healthy living. Reforming the market for targeted health and wellness foods and beverages looks promising!

Are our traditional Ayurvedic medicines waiting for transformation through current modern medical research?

A few questions on all these issues are addressed in this issue of Interlink Insight!

Well, responsible conduct, sustainability thinking, enlarging the health span and a focus on operational excellence would enable significant reformation!

Special feature on International Markets insights of "Pharmexcil & Interlink" combined conference also look at new opportunities.

Looking forward to your response to this new issue of Interlink Insight. On your feedback we thrive.

Hope you have an enriching reading experience.

Yours sincerely,

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Lifting Pharma Industry Image

- Dr. R. B. Smarta



The Pharma industry has not been able to translate its achievements into favourable perceptions that fulfill the expectations of thousands of people. A lack of noticeable trust deficit has hampered the Pharma industry image. Read on to find ways to lift the Pharma industry image.

No stakeholder of the Pharma industry will ever deny that over a period of years, Pharma industry has come out with a number of innovative new products for betterment of health of people in general. Yet, somehow the Pharma industry has not been able to translate these achievements into favorable perceptions that they fulfill the expectations of millions of ordinary people.

A noticeable trust deficit has developed due to lack of transparency, a paucity of continuous, honest and credible information from the industry to patients and visible activities for society.

Perceptions: Ultimate Public Perceptions:

A potent combination of high societal, intervention of Pharma companies, and a significant role of government and economy, necessarily creates conflicts of ultimate consuming public versus industry and government. Facilitators and patients observe that frequent episodes of corporate misconduct or failures exposed by media, give rise to a further negative twist and this represents an unique scenario of low or no trust.

Ethics is a complex and multi-faceted subject, and one that applies to all aspects of health care management and delivery. Marketing practices that are false or misleading can destroy consumer's trust in an organization & or its products. Ethical issues also arise when firms use ambiguous statements in which claims are so weak that the viewer, or listener must infer the advertiser's intended message.

Due to the cause of rise in consumerism, we see reputation related issues as most pervasive which pose threat to the industry.

Patients:

The emotional involvement that patients and their families have with medicines, with the respective companies and with the industry as a whole, is very intense and

complex. They affect their very existence of both sides. On top of it, patient education on drugs is so low that the value of most medicines is beyond comprehension. Besides, the price of the same medicine varies from one retail outlet to another and there is so much competition in every molecule, that there are price variations between different companies as well.

How can a patient comprehend?

Physicians:

The focus of a Pharmaceutical company has traditionally not extended beyond prescription. Some efforts are being made for patient education in health camps. As a result, the interactions between physician and Pharma company have undergone tremendous changes. CRM has been oscillating between creed and greed. That gives reasons for competition to speak more about the transactions and the overzealous role played by media has tarnished the image of physicians too.

How can patients trust on Physicians who are not known to them?

The digital revolution provides countless untapped opportunities for the Pharmaceutical industry to recapture its lost glory.

Regulatory Authorities:

At all levels of drug development and in all stages, especially at clinical trials level, the regulators play an important role.

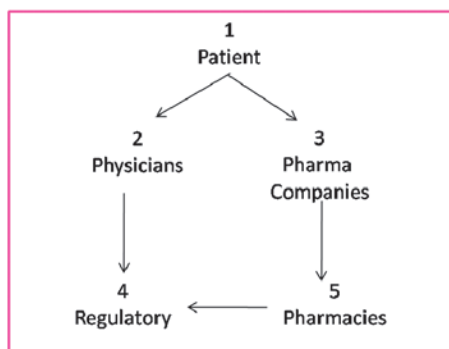
Pharmaceutical products are subject to regulations designed by governments to protect public health.

Even after the product gets into the market, post marketing surveillance, pharmaco-vigilance needs to be taken into account where regulators play an important role.

Licensing to manufacturers and sale of Pharma products has been liberal and hence, many me-too products are available.

Pharmacies:

Many pharmacies have started providing 'Home delivery' for patients in many metros. Strictly insisting on prescriptions and following-up their patients is not a common practice of pharmacists in India. Many substitute the prescribed drugs after informing patients, offering brands of medicine that fetch bonus offers, trade schemes, etc.



Source: Interlink Knowledge Cell

Intermediary Public, Media and Reality of Ultimate Public:

A majority of Pharmaceutical companies, unless they have OTC or food products, have an access towards intermediaries like doctors and hospitals. The final consumers remain in dark about the actual intention and action of Pharma industry for them.

In case of prescription medicines, it becomes more enigmatic and consumers rely mostly on the intermediaries for their decision making.

High level of education amongst patients, the digital revolution making patients aware of health, emerging potent demographics, behavior of media along with government interventions create an atmosphere and context for the perception of the industry.

The Collective Challenge: To Rebuild the Trust:

This image challenge facing the industry is now too big for any individual company to address. Therefore, in order to rebuild the

trust, industry needs to co-operate.

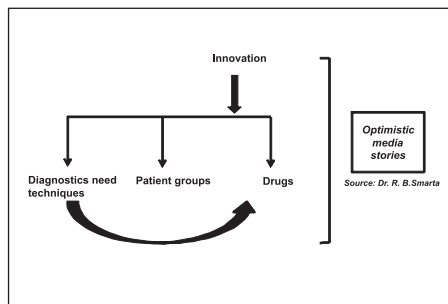
Industry needs to take following seven initiatives:

Initiatives:

1. Innovation:

No one argues that the value of truly innovative medicines is immense. They save and manage patients' lives, give new hope, and improve the quality of life by reducing the need for hospitalization and surgery. Everyone depends, at some point, on Pharmaceutical innovation for their wellness.

These innovative actions need to be communicated in an optimistic way. The following diagram would provide clarity in doing so.



2. Touch Point Impact:

Awareness of the industry's social and economic impact needs to be re-established. An investment in healthcare is an investment in both society and the economy. Healthier nations are also wealthier nations and, consequently, a healthier world is also a wealthier world.

Finally, there can be no trust without honest and open dialogue, and a new spirit of openness is, possibly, the most important theme we need to communicate. Actually, it is much more than that. It is the basis for behavioral change across the entire industry.

3. Save on "Soar to Eye" Promotional Expenditure for Patient's Benefits:

The perception about Pharma industry is that companies spend too much on sales,

marketing and advertising. They also feel it lacks transparency with respect to risks and benefits. As a result, stakeholders believe that marketing focuses too much on sales and not enough on patient treatment of the outcomes.

To regain confidence of the market which includes consumers and all stakeholders, industry needs to bring realignment between the attitudes towards expectations and actions of 'Industry'.

In the face of this challenge, it is important to translate expectations of consumers into specific actions and regain consumer's confidence to redress reputation imbalance.

4. Corporate Activities & Image Promotion:

In order to create the right image and right perception of the industry, industry associations and companies need to invest in adequate promotion.

In fact, "Times of India" has a cell which helps companies to build corporate brands. Except Pfizer, Cipla in recent times, and a few more companies, no specific promotion of companies has been taken place to communicate their work for ultimate public.

On the other hand, many companies like Novartis, Burroughs Wellcome, etc. who have foundations are carrying out an awesome work for patients free of cost without any promotion.

Building an image is a long term process with big investment!! It creates good will!!! And all of us value "Goodwill".

5. Brand India promotion:

Brand India Pharma campaign is a significant initiative being led by Pharmaceutical Export Promotion Council (Pharmexcil) and India Brand Equity Foundation (IBEF) under the aegis of the Department of Commerce, Government of

India. The underlying objective of Brand India Pharma campaign is to highlight the value proposition that Indian pharmaceutical sector holds for the rest of the world.

6. Quality Issues:

For the ultimate public, seeing is believing. As major stakeholders, they expect health solutions at an affordable price. This affordability can come from Pharma companies, health insurance companies or from Government policies. They ultimately expect health solutions.

7. Digital Information and Engagement:

The digital evolution provides untapped opportunities for doctors and also patients to communicate in an efficient and comprehensive way.

Conclusion

Why not establish the industry as the resource leader for healthcare information for both professionals and consumers? It's a massive work but can be taken up on collaborative basis. Immediate tactical innovations will allow meaningful and trusting relationships to be rebuilt and sustained, and would demonstrate a real and binding commitment to patient health and education across the industry, and across the planet. It is very fortunate that our industry is populated by people who genuinely care. And that, above all else, needs to be communicated, loud and clear.

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A Business Case for Training in Business Ethics

- Dr. Ruth D'Souza



The views on both sides of the debate are strong. The question of whether ethics should be taught remains. Read on to get deeper insights on this issue.

The fiscal year 2010-2011 will go down in the annals of Indian history as a year of 'scams'. What began with the discovery of the biggest corporate scandal involving the inflating of profits of the IT global major -- Satyam dubbed by leading economists as 'India's Enron', has turned into a virtual tidal wave of expose's on corruption.

The corporate scandals appear to be a direct consequence of widespread greed. Managers and their lawyers, investment bankers and accountants simply lied to investors for their own avaricious gain. But the root of the problem is not just human nature. It stems from the overriding objective of a company's management to maximize shareholder value, with a philosophy that ends justify the means!

A fact not discussed widely is that the financial crisis has also been driven by widespread ethical lapses. Recklessness also features among the sins underlying the financial turmoil. Then there is the rampant materialism "I-want-it-all-now" mentality. Thus, at the heart of the banking, housing, credit card and job crisis and in general the economic crisis is a crisis in ethics.

There is clearly a trust deficit in leadership in India as well as around the world and a growing sense of frustration at the increasing lack of ethics in public life. Ethics is a real problem which needs to be addressed.

Business Ethics - An Oxymoron?

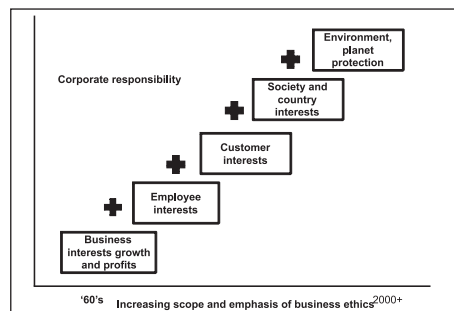
Most large organizations have explicit business values and ethics policies, a key element of which is a code of ethics. Yet on a daily basis the media is full of examples of serious violations involving many of these companies. What are the causes of the apparent gap between having published ethical principles and their becoming embedded in the bloodstream of an organization? Is it true that business ethics is truly an oxymoron?

The term 'business ethics' is generally used to portray two different concepts. First, it

describes the relationship of civil society to the business sector. Second, it involves the interaction of business entities with their main constituents: employees, customers, suppliers and shareholders.

Ethical issues often arise when the desire for short term profit affects the way a business is run. However, these arguments cannot be used as an excuse for business to be unethical. Business does not operate in a vacuum. It operates within the thick of the social environment.

In the face of worsening social and environmental problems, consumers, investors and society in general have begun to call on companies to assume their portion of social responsibility and to conduct their businesses in an ethical manner.



A Problem of Choice– Conflict of Interest

Ethical problems arise not because of people's tendency to do evil, but because of the conflicting nature of standards and interests, which are valid in themselves. Problems in ethical decision-making and behavior occur only when individual interests and social norms conflict with each other.

Research has already shown that ethics do pay. Since unethical practices cost industries billions of dollars a year and damage the images of corporations, emphasis on ethical behavior in organizations has increased over the recent years.

Why Is Business Ethics Needed?

The major reasons behind ethical business practices are:

1.To prevent businesses from abusing the rights of the general public.

2.To protect employees from being subjected to unethical practices.

3.To ensure businesses remain economically viable by complying with the value system of a society in which they operate.

4. To protect business itself from unethical practices of employees.

5.To act as major motivator for ethical employees to achieve a high degree of productivity.

A business cannot afford to have a reputation for not behaving ethically, which can in turn be damaging to its business interests.

What's Driving Business Ethics Today?

The *AMA/HRI Business Ethics Survey 2005* clearly illustrates that businesses view ethics as having a big impact on their brands and reputations as well as on customer trust and investor confidence. Business ethics isn't only about “doing the right thing” or even avoiding the kind of scandals that can utterly devastate a company. It's about good business.

Some of the key findings in that survey on what is influencing ethics in today's organizations, and how business ethics may evolve over the course of the next 10 years are given below:

1. Reason for running an ethical business, today and in the future, is the imperative to protect a company's reputation.

2. Maintaining an ethical business environment has become more important and more challenging in today's fast-changing global marketplace.

3. The pressure to meet unrealistic business deadlines or objectives is the factor most likely to cause people to compromise ethical standards in companies.

4. Business scandals have had a major

impact on business ethics issues in recent years but, in the future, globalization and competition will be the top business drivers of ethics.

5. Laws and regulations are, and will remain, the most influential external drivers of corporate ethics, but issues related to the environment are expected to become considerably more important in the next 10 years.

6. As technologies grow ever more powerful and pervasive, they will raise difficult ethical questions which companies will have to deal with.

7. Globalization brings many ethical challenges, especially in developing nations where issues related to forced labor, child labor, and working conditions are top concerns.

8. Corporate culture is crucial to creating and maintaining an ethical environment, but culture is notoriously difficult to shape and change. Doing so requires a systems framework approach.

9. Leaders who support and model ethical behavior and communicate such values are critical to a company's ethics.

10. Establishing codes of conduct and training programs are seen as the most important corporate practices for contributing toward an ethical culture. Also important are ombudsmen to provide confidential and informal guidance and help lines to officially report malfeasance.

11. Having the right measurements and indicators is necessary to gauge the corporate ethics environment.

12. The companies with best-in-class ethics practices will increasingly gear their strategies toward “external” stakeholders.

13. In terms of serving customers and investors, ensuring transparency is key.

14. The best way of encouraging ethical conduct among suppliers is through codes of conduct and audits.

15. In the near future, companies will seek

ways to become more proactive in terms of dealing with problems that pose, or may soon pose, ethical challenges.

Can Ethics be Taught?

Recognizing the danger of students carrying unethical and wrong beliefs into the corporate world, and in response to the increasing number of corporate scandals, management institutes like the IIMs have now made it mandatory for students to take a course in business ethics.

Yet, the debate is: Can business ethics be taught? Many people feel that ethics is simply something you must learn at a young age. If one subscribes to this view, then ethics education is a waste of time and money. On the other hand, many also feel this is not true. Each of us has faced numerous ethical dilemmas.

The broader question about the source of ethical and unethical behavior is based on the “nature/nurture” debate in psychology. Are we more the result of our genes (nature) or our environments (nurture)? Most studies find that behavior results from both nature and nurture. When it comes to unethical behavior, the answer is not either/or, but and.

The above proposition makes it clear that ethics can indeed be taught. Ethical behavior relies on more than good character. Although good upbringing may provide a kind of moral compass that can help the individual determine the right direction and then follow through on a decision to do the right thing, it's certainly not the only factor determining ethical conduct. In today's highly complex organizations, individuals need additional guidance. They can be trained to recognize the likely ethical dilemmas in their jobs; the rules, laws, and norms that apply in that context; reasoning strategies to arrive at the best ethical decision; and an understanding of the complexities of organizational life that can conflict with one's desire to do the right thing. For example, businesses that do defence-related work are expected to comply with a

multitude of laws and regulations that go far beyond what the average person could be expected to know.

The ethical decision-making process involves three basic steps:

- Moral awareness (recognizing the existence of an ethical dilemma),
- Moral judgment (deciding what's right), and
- Ethical behavior (taking action to do the right thing).

All of these steps are influenced by two types of factors:

- Characteristics of individuals and
- Characteristics of organizations.

The question of whether ethics should be taught remains. Many still believe that ethics is a personal issue that should be left to individuals. They believe that attempts to teach ethics are inappropriate efforts to impose certain values and to control behavior. But this does not negate the responsibility of employers to teach employees what they need to know to recognize and deal with ethical issues they are likely to face at work. Failing to help employees recognize the risks in their jobs is like failing to teach a machinist how to operate a machine properly. Both situations can result in harm, and that's just poor management.

Individuals do come to organizations with predispositions that influence their behavior, but the work environment can also have a large impact. Making ethical decisions in today's complex organizations isn't easy. Good intentions and a good upbringing aren't enough. The special knowledge and skill required for making good ethical decisions in a particular job and organizational setting may be different from what's needed to resolve personal ethical dilemmas, and this knowledge and skill must be taught and cultivated.

Therefore, organizations that neglect to teach their members “ethical” behavior

maybe tacitly encouraging “unethical behaviour” It is the management's responsibility to provide explicit guidance through direct management and through the organization's formal and informal cultural systems. The supervisor who attempts to influence the ethical behavior of subordinates should be viewed not as a meddler but as a part of the natural management process.

Conclusion

Educational institutions and work organizations should teach people ethics and guide them in an ethical direction. Ethical problems are not caused entirely by bad people. They're also the product of organizational systems that either encourage unethical behavior or merely allow it to occur.

While individual characteristics are a factor in determining ethical behavior, good character alone simply doesn't prepare people for the special ethical problems they're likely to face in their jobs or professions. Special training can prepare them to anticipate these problems, recognize ethical dilemmas when they see them, and provide them with frameworks for thinking about ethical issues in the context of their unique jobs and organizations.

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Sustainability: A Key Driver

- Dr. R. B. Smarta

New Market Opportunities - Medical Foods & Dietary Supplements

- Ms. Ankita Dhekne

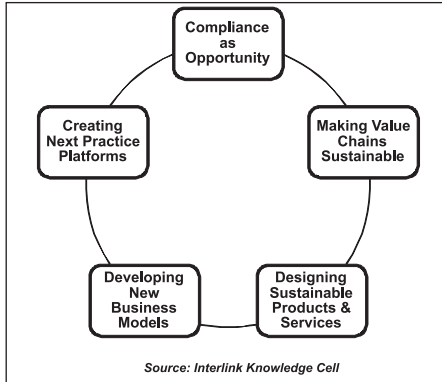
Sustainability: A Key Driver

-Dr. R. B. Smarta

Pharma companies are now focusing on sustainable growth and development. Being sustainable not only helps in realizing bigger dreams but also in lowering costs and increasing revenues. Competitive advantage will be achieved by pharma companies that make sustainability a goal. Read on to know more about sustainable growth and development.

Sustainability earlier was a matter of efficiency in operations. Companies reduced costs to sustain in the business. Sustainability now is a matter of competitive advantage. It is more of if the company innovates, it sustains in the business. Making sustainability a goal requires rethinking business models. It is essential and crucial for realizing the bigger dream.

Five Stages of Sustainability



1. Compliance as Opportunity

The company has to view compliance as an opportunity for achieving sustainability. Compliance is difficult. Environmental regulations vary from country to country. Compliance with the strictest standards early on gives a company a lead position for the future. A company can save money by complying to the gold standard globally. It gives the company a break for innovation.

2. Making Value Chains Sustainable

The drive to be more efficient spreads

throughout the value chain. Being environmental conscious is the primary focus of many large corporations. Many companies are taking up life-cycle assessment as it takes care of environment-related results of value chains. Operational innovations are being focused on to become more eco-friendly.

3. Designing Sustainable Products and Services

Companies are either restructuring their sustainable offerings or developing them to become environment-friendly.

4. Developing New Business Models

Sustainable business models can be created by capturing revenues and delivering services simultaneously. Some companies have developed new models just by asking at different times what their business should be. That's what Waste management, the \$14 billion market leader in garbage disposal, did. Waste management set up a unit, Green Squad, to generate value from waste. Improving value of offerings and developing business models that combine digital and physical structures is vital to achieve sustainability in the business.

5. Creating Next-Practice Platforms

Sustainability can be the driver of innovation. One is evolving at the juncture of the internet and energy management. Called the smart grid, it uses digital technology to manage power generation, transmission and distribution from all

types of sources along with consumer demand. The smart grid will lead to lower costs as well as more efficient use of energy. The concept has been around for years, but the huge investments today will soon make it a reality.

Societal Sustainability

Societal sustainability is the least understood of the ways for approaching sustainable development. Daniel Raphael addresses and divides sustainability into material sustainability dealing with environment, air, water, food, fuel, etc. and societal sustainability dealing with issues that affect individual / family like society, politics/government and economics/finance. The three core values of societal sustainability are quality of life, growth and equality. Societal sustainability can be improved by improving the quality of people and their participation in societal sustainability by incorporating the three core values of social sustainability into the organizations of their societies

Corporate Sustainability

Corporate sustainability is an evolving corporate management model. Profitability and corporate growth are significant in corporate sustainability, but it also stresses on the corporation to pursue societal goals, specifically those relating to sustainable development — environmental protection, social justice and equity, and economic development. Mix sustainable development, corporate

social responsibility, stakeholder theory and accountability, and you have the four pillars of corporate sustainability.

CEO Mindset is Shifting

CEOs are now looking at a new age of sustainability. 93% CEOs see sustainability as a vital feature for the company's progress. Most of the CEOs feel that sustainability should be fully rooted in strategies and operations. As issues of climate change and the natural environment, social development and global corporate governance become ever more pressing, CEOs are acutely mindful of the challenges ahead. These challenges have a direct influence on companies' operations, but also demonstrate the role business must play in addressing the demands of the new century. CEOs are of the view that sustainable development will be a basic assurance for the company's growth and survival.

Conclusion

Sustainability is a smart business. It is not the burden on bottom lines that many executives believe it to be. In fact, becoming environment-friendly can lower your costs and increase your revenues. In the future, only companies that make sustainability a goal will achieve competitive advantage. That is why sustainability should be a touchstone for all innovation.

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New Market Opportunities - Medical Foods & Dietary Supplements

-Ms. Ankita Dhekne

The market for targeted health and wellness foods and beverages is a dynamic and promising one in India, some ancillary segments of Nutraceuticals are poised to become mainstream such as Medical Foods, Foods for Special Dietary Uses, Herbal Supplements etc. On the whole, the opportunities for nutraceuticals are growing as consumers have become aware of healthy living and are demanding more natural & preventive therapies, increasing the healthcare costs and advances in science which have now made it possible to apply new innovations such as nutrigenomics in the field of nutraceuticals. Thus, overall the preventive therapies and alternative treatments are flourishing.

The market for targeted health and wellness foods and beverages is a dynamic and promising one in India, driven largely by increasing awareness regarding their health and importance of having a healthy lifestyle amongst consumers. Also the world over, the consumer's approach is shifting from Curative to Preventive therapy.

Today more and more people have become keen on managing their health and they want to remain healthy, stay fit, thus, are focusing on preventive therapies. Consumers are also becoming more interested in self-care and hence dynamically seeking nutritional and healthy products (Nutraceuticals) to maintain their daily nutritional requirement's balance. There is a status shift in the Nutraceutical industry as a result of patients transitioning from passive healthcare recipients to active healthcare consumers.

Consumer awareness regarding healthy lifestyle and their focus on preventive therapies is one of the major drivers of Nutraceutical industry especially in India. Nutraceuticals comprise of 3 segments viz. Dietary Supplements, Functional Foods and Functional Beverages.

Amongst these segments, Dietary supplements are presented in drug formats such as capsules, tablets, soft gels, etc. Functional foods are presented in food or

other eatable formats such as biscuits, gummies, snack bars, etc. Functional beverages are presented in the form of beverages such as ready-to-drink teas, sports and performance drinks, energy drinks, fruit drinks, enriched water, etc.

Other ancillary segments of Nutraceuticals that are poised to become mainstream are; Medical foods, Foods for Special Dietary Uses, Herbal supplements etc.

Along with the growing need for Nutraceutical products, the advances in science have given rise to opportunities and innovations in the field of Nutraceuticals across its various segments.

Medical Foods

Medical foods or Food for Special Medical Purposes are principally formulated food products intended to be used under the supervision of medical and other appropriate health professionals (e.g. dietitians, nurses and pharmacists). These products assist the dietary management of individuals (including children) with chronic disease, disorders or medical conditions, or during acute phases of illness, injury or disease states.

Medical foods are portmanteau between dietary supplements, pharmaceuticals and food.

The medical foods category is expected to play an important role in health and quality of life beyond prescription drug therapies

Opportunities

- The Medical foods market has ample growth and diversification opportunities in India as well as the world over. Medical foods market revenues are expected to reach approx. US\$ 4.2 billion in 2017 (India) and globally the market is expected to reach US\$ 40.1 billion by 2018, thereby exhibiting a 2008-2018 CAGR of 5.8 %.
- The Medical foods market is expected to grow significantly as there is a great need for health benefit products and cost effective healthcare.
- Being in a unique space between dietary supplements, pharmaceuticals and foods, the Medical foods category may offer novel growth for research-focused companies.

Trends currently observed in the Medical foods industry include movement to mainstream medical use and growing awareness of medical foods. Medical foods are now offered in tablet and capsule form, which enable them to be easily distributed by prescription.

- Medical foods are composed of GRAS ingredients, which generally have a low toxicity making them safe for use. In contrast, drugs can be harmful and cause severe side effects. Advances in food technology allow expansion in Medical food manufacturing.
- Medical foods are predicted to grow strongly, in light of the increasing use of them in long-term care and increasing incidence of age related disorders.
- Medical foods have been awarded orphan drug status by the FDA, and this has reduced its cost of production and time required to bring them to market, particularly in the clinical trial stages.
- Some drug therapies are not completely successful in the treatment of diseases thus presenting Medical foods as a cost effective option.
- Several other research and commercial opportunities contribute to a favorable

risk-benefit ratio for Medical foods, and are believed to create an environment that will foster the continued use and expansion of medical foods.

Probable Challenges to Overcome

Although Medical foods are a distinct regulatory category and therapeutic class of products, general awareness amongst end users (patients) as well as the medical community is low and often they are confused with dietary supplements. There is a need for more clinical research in this area to help physicians overcome the ignorance and to prove that these compounds work as well or even better than traditional prescription drugs.

The real challenge in use of Medical foods is to encourage physicians to consider the nutritional status of patients, and enhance their understanding of the altered nutrient requirements inherent in a diseased state.

Adoption of Medical foods will be driven largely by its efficacy in managing the increased nutritional requirements imposed by, or associated with diseased states. Apart from the above mentioned aspects, there is also a strong need for regulatory clarity, developing customized products, affordable pricing and distribution strategy as this is a comparatively new segment.

Dietary Supplements

Dietary supplements are defined as any product that can be taken by mouth and contains a dietary ingredient intended to supplement a diet. Dietary Supplements are not intended to prevent, treat or cure any disease. Dietary ingredients in these products may include vitamins, minerals, herbs, or other botanicals, amino acids and substances such as enzymes, glandular tissue extracts, metabolites, etc.

The excitement about dietary supplements among the population keeps growing more than ever as they expand their reach to new market levels across the globe. Recent industry efforts to curtail regulatory challenges along with the rapid rise of

personalized nutrition in the form of Medical foods are changing the dynamics in a highly competitive marketplace.

Opportunities

- Advances in science and technology, such as in the field of Nutrigenomics, Metabolomics and Proteomics, etc. coupled with innovative delivery systems/formats may open up new opportunities for the dietary supplements market.
- Bright prospects of growth persist for the sales of Dietary supplements needed to help fill nutritional gaps in healthy people who do not need Medical foods, or who may not meet their daily nutrient requirements. In these cases, protein supplements, minerals, probiotics and fish oils/omega fatty acids will likely remain the top performers as evidence continues to prove that they indeed may help people prevent certain chronic conditions and maintain their health.
- The use of natural, plant-based ingredients have shown to be successful in managing metabolic processes associated with many conditions or diseases. This has lead people to seek for natural, nutritional supplements and other alternatives to the conventional medicines/ drugs.
- Impelled by the aging populations and heightened interest in preventive health, sales of nutritional and herbal supplements have surged globally. The sheer numbers of ageing or baby boomer population are expected to shift spending in healthcare and realign markets, creating considerable new opportunities for the dietary supplements market.
- The above mentioned phenomenon is already visible in the vitamin & mineral specific dietary supplements business, where purchases have grown by 6 percent annually from 2007-2012, much of this coming from eye, bone and joint supplements. As of 2012, consumers (older population) accounted for 36% of U.S Vitamin, Mineral and Health

Supplement sales, a trend that is expected to continue for the foreseeable future.

- Among the various opportunities for the growth of Dietary supplements market one is the penetration in rural markets. Penetration of semi-urban and rural centers will be the key to mass market reach of Nutraceuticals.
- One of the key growth drivers for dietary supplements is online sales in the Western market with an increased interest in Eastern health and wellness products. As the alternative medicine trend continues to grow, it is likely that demand for Eastern products will accelerate, especially among younger consumers.

Today the easy and more convenient online access to these products will help companies leverage this growth opportunity.

- Consumers are becoming increasingly aware of the innovative supplement ingredients and delivery mediums due to which many previously specialized supplement categories are becoming mainstream. These specialized supplement categories also pave way to great opportunities.
- Promotion of products according to the need & interest of different cultural groups in India can be beneficial for Dietary supplement manufacturers. For instance, Vitamin E from a non-vegetarian source is not well-accepted in certain cultural groups. Therefore, providing these groups an equivalent vegetarian variant with similar health benefits will help Dietary supplement industry better penetrate this area. Taking into consideration the cultural aspects will provide even more opportunities.

Probable Challenges to Overcome

In 2013, Dietary supplements contributed 31%, Functional foods 33% and Functional beverages 36% of the total global Nutraceutical market share. In 2018, Dietary supplements are expected to contribute 23%, Functional foods-47%

and Functional beverages-30%.

Thus, it can be observed that even though Dietary supplements market is expected to grow, the growth is at a slower rate compared to the other segments. This can be attributed to the fact that Functional foods & beverages fit as well as blend easily and more conveniently into consumer's changing lifestyle, at the same time the acceptance of older/conventional formats such as Dietary supplements could get mixed up with drugs as the forms are like Pharma.

There is a need to position Dietary supplements clearly in the minds of consumers, as it will play an important role in growth, development as well as widening the consumer base.

Conclusion

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The Nutraceutical Potential of Ayurvedic Medicine

- Dr. Dilip Ghosh



It was not long ago that Ayurvedic medicines and Ayurveda-derived dietary supplements were only found in a handful of health food stores in both India and abroad. This has changed. Gain a comprehensive outlook on the Nutraceutical potential of Ayurvedic medicines.

India is known for its traditional medicinal systems – Ayurveda, Siddha, and Unani, which are mentioned even in the ancient Vedas and other scriptures. The Ayurvedic concept appeared and developed between 2500-500BC in India.

The inner meaning of Ayurveda, “science of life,” comes from the ancient Indian system of healthcare, focused on views of man and his illness. In Ayurveda, the positive health means metabolically well balanced human beings, which offers a complete system to live a long healthy life (“science of longevity”) through diet and nutrition.

It was not long ago that Ayurvedic medicines and Ayurveda-derived dietary supplements were only found in a handful of health food stores in both India and abroad. These days, however, it is difficult to find a health food store that does not have Ayurveda-based herbal products on the shelf. And even in mainstream channels, food, drug and mass market grocery stores, duty free airport stores are starting to recognize the value of this class of herbs. Indeed, today a consumer does not have to go far to find products based on this ancient Indian system of medicine.

From Cure to Prevention

In the 21st century, oriental medicinal herbs are gaining importance in mainstream healthcare, as greater numbers of people seek relatively safe remedies and approaches to healthcare. The demand for herbal medicines, herbal health products, herbal pharmaceuticals, nutraceuticals, food supplements and herbal cosmetics etc. is increasing globally, due to the growing recognition of these products as mainly non-toxic, having lesser side effects, better compatibility with physiological flora, and availability at affordable prices. The earliest records suggest that herbal medicines have been used and documented in Indian, Chinese, Egyptian, Greek, and Roman medicinal systems for about 5,000 years. Traditional herbal medicine has also been practiced from ancient times in American and Arabian countries, and Japan. The transcripts of classical traditional medicine systems in India include Rigveda, Atharveda, Charak Samhita and Sushruta Samhita. Folk (tribal) medicines

are also important sources for the indigenous healthcare system. India has been known to be a rich repository of medicinal plants from ancient civilizations.

Inside Ayurvedic Medicine

Ayurveda is a lifestyle science that was developed in India nearly 5,000 years ago. It is a holistic science based on a philosophy that good health comes from integrating all aspects of life such as herbs, food, exercise, yoga, massage and more. According to classical Ayurvedic theory, we are all born with a unique constitution referred to as Doshas; a mix of Vata, Pitta or Kapha. Each is present within our bodies and has a job to do. Vata is responsible for all motion, Pitta for all metabolic activities, and Kapha for maintaining the right amount of fluids in the body (i.e. water, blood, mucus, phlegm, etc.) While all of us must have the three Doshas in our body to exist, we are born with a combination of these forces that is rather unique to each of us. This combination helps define our physical, mental and emotional make-up that keeps our body in homeostasis and in turn the healthiest state we can be.

When the body goes out of this balanced state, disease can eventually occur. Hence, Vata imbalances are exhibited in health conditions that have to do with movement, such as joint conditions. Pitta imbalances lead to all types of metabolic and digestive diseases. Kapha imbalances most often involve excess of fluids, such as conditions of the lymphatic system. Dr. C. K. Katiyar, CEO, Emami Healthcare defined Ayurveda as: “science of life rather than system of medicine to Western World.”

Dr. Ashok Vaidya, another pioneer researcher and Research Director, Kasturba Health Society-Medical Research Centre described Ayurveda as: “The foundation which comprises of a healthy and non-indulgent lifestyle, harmony of the internal and external environment through simple measures and wisdom of being a kind person.”

Dietary Aspects of Ayurveda

In Ayurveda, the importance of a particular

Common Name	Uses
Shatavari	Rejuvenative, Supports women having hysterectomies; Aids to maintain clean urinary tract; Strengthens immune system and purifies blood
Brahmi	Memory enhancer; Mental and physical fatigue; Insomnia; Anxiety; Attention deficit-hyperactivity disorder (ADHD); Tonic to fight stress
Indian frankincense	Respiratory ailments; Digestive disorders; Joint pain and inflammation; Asthma; Arthritis; Inflammatory bowel diseases.
Guggul	Immuno-modulating properties by enhancing white blood cell count; Joint health; Lower cholesterol and triglycerides, while maintaining the HDL to LDL ratio.
Garcinia	Helps reduce body's ability to store fat; Lowers body weight through appetite control; Lowers serum triglycerides; Creates a process in the body called thermogenesis; Helps with catarrhal conditions of the throat, urinary system, and uterus
Neem	Used as a tonic and astringent that promotes healing; Antispasmodic and detoxifying properties; Beneficial effects on circulatory, digestive, respiratory, and urinary system
Indian Long Pepper and black pepper	Stimulant for both the digestive and the respiratory systems and has a rejuvenating effect on lungs; Enhance thyroid hormone level; Also enhances bioavailability and absorption of other active ingredients
Guduchi	Anti-bacterial; Immunomodulator
Ashwagandha (Indian Ginseng)	Increase energy, youthful vigour, endurance, strength, and nurture the time elements of the body; Increases vital fluids, muscle fat, blood, lymph, semen and cell production; Counteracts chronic fatigue, weakness, bone weakness, loose teeth; Helps to invigorate the body by rejuvenating the reproductive organs
Ginger	Enhances absorption and prevents gastrointestinal side effects; Improve digestion and to prevent nausea; Anti-inflammatory; Anticancer
Adapted & modified from Pandey et al. 2013, Evi. Based Comp. Alt. Med.)	

Table 1: Selected Ayurvedic Herbs Having Nutraceutical Potential and Their Primary Use in Traditional Medicine

diet in the prevention and treatment of diseases was well known even in 1000BC. For ages, people in India, because of their cultural beliefs and experiences, have taken herbs and herbal formulations as part of their daily food supplements. The faith in the power of botanicals, along with the availability of a vast majority of different kinds of herbs in India has always been a thrust behind the survival of this scientific

art of healing.

“Tat cha nityam prayunjeet svasthyam yen anuvartate. Ajaatanam vikaranam anuttpattikaram cha yat” (Charaka Samhita: Sutra Sthana: 5)

[The diet which besides providing the basic nutrition to the body, helps to maintain the healthy state of the body and prevents the occurrence of diseases should be consumed].

The science of food and nutritionals in Ayurveda was so developed that Charaka (an Ayurvedic Scholar) has categorised all the food items into twelve classes: corns with bristles, pulses or legumes, meat, leafy vegetables, fruit, vegetables which are consumed raw, wines, water from different sources, milk and milk products, products of sugarcane, food preparations, and accessory food items such as oils and salts, and has further sub-categorized these food groups.

Another classification is based on the consistency of food products: Peeta (liquid in consistency, advisable for the newborns, children and diseased people and advocated in summer), Leeda (Paste form that can be licked, advisable for children, convalescing and old people), Ashita (semi-solids, advised for aged people) and Khadita (solid food, advisable for young people with good digestion).

It is interesting to learn that Ayurveda lays a great emphasis on the quality of nutritious food for:

- I. averting the degenerative changes caused by aging (Rasayana),
- II. convalescence after an illness (Balya),
- III. enhancing the defense system (Roga Pratibandhaka Rasayana),
- IV. maintaining the vigor and vitality (Vajikarana), and
- V. for maintaining the joie-de-vivre (Jeevaniya).

The category of Rasayana drugs is divided into three categories;

- ☐ Kamyā (for vitality, intellect etc.),
- ☐ Naimmitika (for specific disorders) and
- ☐ Aajasrika (general); the last one dealing with the daily consumption of
- ☐ Specific food products to rejuvenate the body.

These food products are said to improve the quality of life by offering protection from internal and external stressors.

The usage of Nutraceuticals as advocated by Ayurveda can be also classified depending upon the age of the individual, season of consumption, time of consumption, physiological conditions and according to the target organ.

Nutraceutical Potential

Dietary supplements, including herbal, are popular complementary or alternative products for people. These are the supplements that are intended to supplement the diet and contain one or more dietary ingredients (including vitamins, minerals, herbs or other botanicals, amino acids, and other substances) or their constituents. These are intended to be taken by mouth as a pill, capsule, tablet, or liquid and are labeled on the front panel as being a dietary/food supplement or as Nutraceutical.

These botanicals are sold in many forms as fresh or dried products, liquid or solid extracts, tablets, capsules, powders, tea bags, and so forth. For example, fresh ginger root is often used in various food stores; dried ginger root is sold packaged in tea bags, capsules, or tablets, and liquid preparations made from ginger root are also sold in the market. A particular group of chemicals or a single chemical may be isolated from a botanical and sold as a dietary supplement, usually in tablet or capsule form. An example is phytoestrogens from soy products.

India is the largest medicinal plants producer. There are currently about 250,000 registered medical practitioners of the Ayurvedic system, as compared to about 700,000 in modern medicine. In India, around 20,000 medicinal plants have been recorded; however, traditional practitioners use only 7,000–7,500 plants for curing different diseases. The proportion of use of plants in the different Indian systems of medicine is Ayurveda 2,000, Siddha 1,300, Unani 1,000, Homeopathy 800, Tibetan 500, Modern 200, and Folk 4,500.

In India, around 25,000 effective plant-based formulations are used in traditional and folk medicine. More than 1.5 million practitioners are using the traditional medicinal system for healthcare in India. It is estimated that more than 7,800 manufacturing units are involved in the production of natural health products and traditional plant-based formulations in India, which requires more than 2,000 tons of medicinal plant raw material annually.

More than 1,500 herbals are sold as dietary supplements or ethnic traditional medicines.

Some common medicinal plants having nutraceutical potential and their primary use in traditional medicine are listed in table 1. Dr. Katiyar suggested future potential blockbuster formulations such as Aswagandha (*Withania somnifera*) with multi vitamins and minerals and traditional Chyawanprash with vitamins supplementation.

A New Era of Ayurveda

Recent research has shown that consumers are beginning to accept the premise that there is no “magic pill” and that good health comes from integrating all aspects of life. Herbal therapies, diet, exercise and vitamins all work better when used as part of a lifestyle plan. Ayurveda has embodied this principal for centuries.

As Westerners seek ways to devise a healthy lifestyle plan, they will find Ayurveda offers all the tools they need to take care of their health on a daily basis. This may explain the resurgence in the acceptance of Ayurveda. As the awareness of Ayurveda increases in the West, so will the consumer demand for Ayurvedic herbs. Some will follow classical Ayurvedic recipe and devise a lifestyle plan based on their Doshas (Vata, Pitta, Kapha). Many others are positioned as dietary/food supplements or nutraceuticals for mass market penetration.

Evidence-based Products with Proven Functionality from Ayurvedic Domain:

Keen Mind:

Keen Mind is the result of over 40 years of research. It demonstrates benefits for enhancing memory retention and recall, improving mental clarity and focus, as well as assisting learning, concentration and attention. Keen Mind contains a special extract called CDRI 08 which is made from an Indian Ayurvedic herb, *Bacopa monnieri*. It is a natural nootropic (well tolerated cognitive enhancer) designed to improve and protect brain function. Numerous double blinded

placebo controlled randomized studies on KeenMind have provided an excellent platform to assess the utility of treatment in humans for maintenance and improvement of cognitive functions, and normal cognitive aging. Keen Mind is very useful to facilitate learning and concentration, particularly in children and students. This can be used for mature and elderly individuals to aid memory and reduce decline in mental performance. Those with intellectually demanding jobs or who are under pressure, Keen Mind supplementation is promoted as the ideal choice.

CurcuWIN:

CurcuWIN, a new formulation of curcumin with a combination of hydrophilic carrier, cellulosic derivatives and natural antioxidants significantly increases curcuminoid appearance (46 times) in the blood in comparison to unformulated standard curcumin. Curcumin is known for its antioxidant and anti-inflammatory properties and extensively studied for various risk factors and disease conditions. There is potential industry confusion between turmeric and curcumin. Curcumin in CurcuWIN refers to three curcuminoids naturally found in turmeric. CurcuWIN utilized patented UltraSOL Dry Nutrient System Technology for enhancing solubility and bioavailability of lipophilic compounds with a strong support of well controlled randomized human trial. Crystalline curcumin is converted into a molecular dispersion with food grade excipients and antioxidants to make this compound more water soluble.

Songha Night:

Songha Night is a combination of valerian (*Valeriana officinalis*) and lemon balm (*Melissa officinalis*) that restores sleeping patterns naturally who suffer from poor quality of sleep, restlessness, irritability, tension or have problems falling asleep. Valerian has a calming effect on the central nervous system, balancing agitated states, while lemon balm has a soothing effect. Songha Night is a safe and well-tolerated combination of Valerian and Lemon balm (*Melissa*) extract. It represents a natural

alternative to benzodiazepines in the prevention and treatment of mild to moderate sleeping problems. Two double blind, placebo-controlled clinical studies showed that Valerian, alone or in combination with Melissa, showed anxiolytic properties and produces a significant decrease in subjectively evaluated sleep latency and a significant increase in sleep quality.

Mainstream Potential

The association of Nutraceuticals with traditional Ayurvedic medicine is bound to bring long lasting consumer acceptance. When supported by current modern medical research, the acceptance is whole hearted. The three examples quoted above are of the few evidence-based, clinically proven Nutraceutical products picked in from list of ground breaking natural products coming from Indian Ayurvedic domain.

Numerous Nutraceutical combinations have entered the international market through exploration of ethno-pharmacological claims made by different

traditional practices without robust quality, safety and efficacy proof. Honestly speaking, more evidence is needed before these products can be broadly integrated into national health systems for disease prevention for which they have promise.

Despite very strong traditional use, the nutraceutical potential of Ayurvedic components is still not very promising on the global market. Dr. Katiyar analyzed the reason as: “lack of policy support at a domestic level.” On the other hand, Dr. Vaidya notes: “The Government of India paid only lip service to Ayurveda and missed out on the global opportunities. The Indian drug industry was busy making money with copied branded generic drugs and showed no interest whatsoever in Ayurvedic research and standardization.” Dr. Vaidya is a great supporter of reserve pharmacology and he believes: “The CSIR-NMITLI program of Ayurveda-inspired herbal drug discovery based on this principle was a path-breaking effort in diabetes, arthritis and hepatitis. The hits, leads and candidates from this national R&D networked research are outstanding.”

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Overseas Marketing Strategy With Special Focus on Latin America, Africa and CIS countries



Pharmexcil-Interlink Special Issue

Why consider the emerging markets of Latin America?

Demographics in the Latin American Market – The Latin American Population was estimated to be about 581.4 million in 2012. The population growth rate in the region stood at 1.2% annually. Male – Female ratio in Latin America was estimated to be 0.977. As per the demographic divide the age profile of the population is as follows:

- o About 27.56% of the population in Latin America is between the ages of 0-14.
- o About 65.46% of the population is between the age group of 15-64.
- o Only 6.98% of the total population here is 65 years and above.

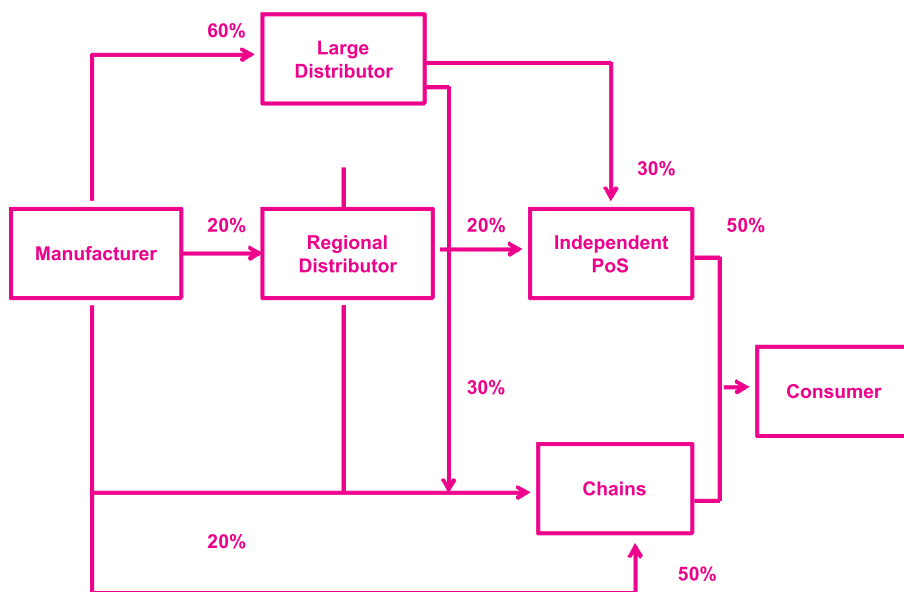
Pharmaceutical Market Scenario – Pharma market in Latin America stands at around USD 63 billion. The major markets in Latin America are Brazil, Mexico, Argentina, Venezuela, Colombia, Chile and Peru. (This portion does not include Mexico while above, Mexico is included. Better we speak of South America excluding Mexico.)

Small individual market sizes along with the travelling complications make the situation unfavorable for the Caribbean. In 2002-2003 with regards to the regulatory aspect, a facility of local registration was available for Central America which no more applies now. It implied that if you register in one country in Central America, then that registration was applicable in all the 7 countries. This facility is not applicable anymore making this aspect less attractive for the companies interested in entering Central America.

Brazilian Market – As Brazil is the largest market in Latin America, we highlight the details here. The GDP of Brazil was USD 2.253 trillion in 2012 as per the World Bank report. The annual GDP growth rate was estimated to be at 1% while the GDP per capita stood at USD 12,789.

There is a great scope for Brazil to grow. The current economic scenario has also seen that the unemployment rate has gone down to 6% from 11% over the last nine years despite the slow-down in the world economy. The average real income at constant rate is also increasing as is the per capita income in the past 8-9 years. The social inequality in the country is also reducing as the GINI index for Brazil stood at 54.7 in 2009 as per the World Bank report. When taking a look at the economic distribution, the maximum development is in the region of Minas i.e. Belo Horizonte city, Rio de Janeiro, Sao Paulo, Curitiba & Porto Alegre. If the population and economy of these five cities is considered then the GDP of 55% would show a high concentration. The rest of the regions including Amazonian Jungles, also are growing well. So, there is a sustainable growth seen in Brazil. Another factor for growth in Brazil is the demographics of the country. The population here is much younger as compared to Europe, so their earning capacity is higher resulting in increased spending. The growth is further fuelled by the fact that an increasing number of people are getting covered in insurance, using one form or another. Also, in the government hospitals in Brazil the underprivileged people are given free treatment but the medicines there are not free. The cost of medicines is actually more than the treatment. As the coverage of people increases, so does the pharma market in the country! Regulatory Perspective – The Agência Nacional de Vigilância Sanitária (ANVISA) is the Brazilian regulatory body for regulation and approval of Pharmaceutical drugs. The ANVISA is a governmental regulatory agency which is characterized by its administrative independence, financial autonomy, and the stability of its directors.

The total market size of the Brazilian Pharmaceutical market is estimated to be at US\$ 25.6 billion in 2011 and expected to grow at a CAGR of 12%. The two categories that have seen the highest growth are pure generics & branded generics. Minimum growth was seen in originators. Even as branded generics make the largest segment pure generics make 17% as per the latest reports. One more category is of that of “Bonificados” which is fairly large now but is declining giving its space to Generics. Another vital factor to consider is the dynamics of the distribution in Brazil concentrating on large national distributors. Drug store chains, small in number, make a large percentage of sale 50 %, (refer Fig.1)



(Fig. 1) Distribution Dynamics in Brazil. Source: IMS

A noteworthy initiative by the government of Brazil is the Farmácia Popular program which is the brain child of the current President, Dilma Rousseff. This market can be a good opportunity as the market is large and there are not many operators because of the price pressure. Also, there are additions to the list of molecules under this program.

The key to getting dossiers ready is to get them filtered, analysed or critically checked by a local consultant who has close liaison with ANVISA. The record of Indian success with dossiers is comparatively low.

The regulations in Brazil state that Pharma equivalence will have to be done within the country (i.e. Brazil) only. The reason why bio-equivalence is allowed outside Brazil is because one visit a year is good enough while 3-4 visits are needed for approving Pharma equivalence centres which is not easy for ANVISA. Also, in case any queries are raised they come with a notice that if not replied to in 60 days then the dossiers filed would be archived. In such a situation, one has to begin at zero level and may have to wait for another 3 years.

Therapy Segments – If we consider a growth opportunity through therapeutic segments, gynaecology is the second largest. But, the penetration of generics in this segment is low. Most of the products offered under this segment are hormonal products; the mono-phasic, bi-phasic, tri-phasic. Therefore, another great avenue for Indian players is to enter into gynaecological hormones.

Despite all of this, Brazil is a good market because of good realisations, less competition even from Indian companies and future growth prospects.

This content is based on the thoughts shared by Mr. Amit Dave during his talk on 'Strategies for Marketing Formulations in Latin American Countries' at Pharmexcil Seminar on 'Overseas Marketing Strategies' in Sept'13.

Mr. Amit Dave is currently working with Zydus Cadila as Vice President with focus on LA business development. In the past, he was heading International Strategy function in a large healthcare company and has had a good exposure to practically all the international markets.

How can one capture a piece of the growing CIS market?

Demographics & Economic Statistics – CIS is part of Commonwealth of Independent States but they are nowhere in common. They are all ex-soviet countries and Russia is a part of CIS but the Russian Federation in itself is a very big market. The population of CIS countries is 276 billion. The GDP here is USD 1.6 trillion and the expected growth rate is about 3.4%. These countries offer a great potential, although every market is quite different from the other; the one common factor here is the language.

Pharmaceutical Market Scenario – In 2009, the Pharmaceutical market was at USD 23 billion and it has reached USD 27 billion in 2012 at an annual growth rate of 10%. If compared to Central Eastern European and Balkans, CIS countries are a fast growing market. Some of the CIS countries with good potential are Ukraine, Kazakhstan and Uzbekistan. If you see the growth potential in these countries, Ukraine went from USD 2.7 billion in 2009 to USD 3.7 billion in 2012; Uzbekistan reached USD 961 million in 2012 from USD 500 million in 2009 while Kazakhstan has reached USD 1.5 billion. The growth rate in Uzbekistan was almost 35% followed by Kazakhstan and Ukraine. Their very high pace of growth offers a big scope for Indian Pharmaceutical companies.

CIS	Pharma Market in 2009 (in million USD)	Pharma Market in 2012 (in million USD)	Growth Rate, PY
Russia	17500	19661	10%
Ukraine	2674	3767	18%
Kazakhstan	975	1492	31%
Uzbekistan	520	961	35%
Belarus	653	757	16%
Azerbaijan	240	498	14%
Georgia	235	191	9%
Moldova	179	1667	21%
Kyrgyzstan	110	149	N/A
Armenia	112	94	3%
2009 figures include DLO & Hospital figures too.			

(Fig. 2) Pharma Market in CIS countries in 2009 and 2012

Therapy Segments in CIS – The therapy areas which have the largest market share in the CIS countries are cardio-vascular at 23.6%, genitourinary systems, sex hormones, elementary tract and respiratory tract. The cardio-vascular segment is displaying a phenomenal growth of almost 20% followed by respiratory segment. Although anti-infective segment is the most popular among aspiring Indian companies here and offers a good initial cash flow, cardio-vascular, gastro and urinary tract are niche segments and could offer very good bottom lines. So, Indian companies can turn their focus towards these segments as well.

Key factors in CIS countries – The factors here are for CIS countries and Russia is excluded here. In first half of 2013, the markets have seen a business of 4 billion dollars. The per capita consumption for these countries was significantly high at USD 50-54 per person. The biggest factor for growth in the CIS countries is imports which have a market share of almost 78.6%. Another key growth factor is generics, under which prescription is a major segment; in other words branded generics are a big factor for the market growth.

If a comparison is made between first half of 2012 and first half of 2013, the market has seen a growth of 16% in terms of value and about 5% in terms of quantity. One more growth factor in

these countries is the epidemic of flu.

Every year for about three months almost every CIS country experiences an epidemic of flu. Another three months are required for budgets and planning. Identifying these six months would work in the favor of the pharmaceutical companies. In fact, Q1 saw strong growth rates in these markets as there was a flu epidemic here. But, the growth rate cooled down in the second quarter.

Major companies in CIS countries – The number one company in the overall CIS market is Sanofi, Berlin-Chemie comes in at number two followed by Novartis, GSK and Bayer. Novartis could have been on the highest position but it misses the position because the company is not among the top five companies in Kazakhstan. Bayer and GSK have performed well and taken the top positions in the market; they have out-performed Nycomed & Gedeon Richter. Although we have a great scope to get into the top 5 in the CIS markets no Indian companies are there in that cadre. Indian companies can offer good quality and these markets are big, but the right focus would ensure Indian companies reached there. Here are the top ten companies in terms of RX and OTC segments.

RX segment				OTC segment			
Rank	Corporation	Share in RX,	Growth, %	Rank	Corporation	Share in RX,	Growth, %
1	SANOFI	4.54	15	1	NOVARTIS	4.89	30
2	GSK	3.86	18	2	BERLIN CH/MENARINI	4.49	22
3	BERLIN CH/MENARINI	3.18	18	3	SANOFI	4.45	9
4	GEDEON RICHTER	2.99	8	4	BAYER	3.81	25
5	ROCHE	2.66	42	5	FARMARK	3.79	12
6	ARTERIUM	2.57	25	6	TEVA	2.98	9
7	NOVARTIS	2.50	35	7	STADA ARZNEIMITTEL AG	2.63	21
8	SERVIER	2.38	15	8	ACTAVIS	2.22	15
9	KRKA	2.20	16	9	BIONORICA AG	2.08	29
10	TEVA	2.02	9	10	DARNICA	1.77	36
Total Top 10		28.89	19	Total Top 10		33.10	20

(Fig. 3) Major companies in CIS countries under RX & OTC segments

More or less the list remains the same, expect for FARMARK and ARTERIUM which are Ukrainian companies. Teva has come into the top ten companies in these markets because of acquisitions. They have taken over Barr Labs which has Pleva, a Croatian company and they had a major share in these CIS markets. So, they have suddenly featured into the top ten markets in the CIS countries. That is a very good way of getting into the top ten regimes; especially if the resources are available.

Russian Market

Russia constitutes almost USD 19.7 billion of the entire Russia & CIS market at 27 billion. The market was estimated to have grown by 12% in 2011. The Russian market is segregated into three categories; DLO, Hospital segment and Out of Pocket market (OOP) i.e. the private market. Strangely, after disbursement, the DLO market has declined and has been taken over by the private market. This is because the government reimbursements are less; DLO payments are delayed & even defaulted on them. So, distributors don't encourage any work with DLO. So, the focus of any company should be on the private market if any company wants to enter the Russian market. One of the driving factors for growth in 2013 is the retail sector as it has performed very well in H1. The reasons for the growth in this sector are price increase and the epidemic in the first quarter. According to IMS forecast, the

Russian Pharmaceutical market is expected to reach USD 27 billion by 2017. It is a good opportunity for Indian companies as the market has good potential.

Growth Drivers in Russia – The growth drivers in Russia are the price increases from the essential drug list (EDL) segment and the introduction of drugs insurances. Even now drug insurance is not a major part of the Russian and CIS economies but companies into drug insurance are slowly coming in. Also, with the introduction of these drug insurance and private insurance companies, the cost of therapies would also rise and the market would increase.

Constraints in Russia – One of the big constraints are the many entry barriers. Also, entering the market can be expensive but on the flip side, the returns are high. Another major constraint is the slow economic recovery. But even as there are constraints, the Russian market is most likely to grow as the country has natural resources, oil and gas. Also, there would a rise in the hospital purchases and overall the market would continue to remain positive.

Distribution in CIS countries – A company must have a well thought out entry strategy if they want to enter the CIS markets. One cannot just give products to a distributor on credit and expect good business. In such a situation, the goods would be with the distributor and eventually expire. The company would get the impression that the CIS markets are not good. Distribution in Russia and CIS countries is a completely different game. For instance, in Ukraine, there are top four distributors. At a time, distributors like BaDM & Optima have a turnover of about USD 1 billion a year and their job involves just distribution, not marketing the product. The important thing to do here is identifying the partner as a distribution company just put the products in the channel, they do not market any product. But, there are a few marketing companies in these markets as well so the key is to go to the markets and identify. Knowing the language would work in favor of the Indian company. This region offers a great opportunity but the marketing has to be done with as much as conviction as done in India. For instance, the market has not seen the use of Cefixime or Cefepime yet and has yet to come out of 3rd generation cephalosporin. So, there is a lot of scope in the market. Success can be achieved in these markets if the same structure as in India can secure the funds, be it by having their own subsidiary or by tying up with a distributor.

Regulatory Challenges – Regulatory challenges are big in these markets. Starting with Russia, the cost of registration here is very high. One product registration would cost you somewhere around USD 150,000 to USD 275,000 because BE and clinical trials have to be conducted locally. So, the cost significantly goes up. The registration time is 2-3 years or even more. So, if planning to enter Russia, it is better to go there with the best of consultants and have a longer horizon in mind; for instance have a business plan for say 10-20 years.

Conclusion – The best way to enter Russia right now is to have a manufacturing JV. It would be the best thing to do if companies have enough muscle power, going for a manufacturing JV because the government is all in for companies who are supporting companies who are putting a manufacturing base out there. Also, countries like Ukraine, Belarus, Tajikistan, etc. have started with inspection and the regulations are getting increasingly stringent with each passing year. So, it is important to have the foresight and be prepared for the years to come. When planning to enter the CIS countries, the Indian image, strategy of building brands as well as the legal framework has to be considered. To sum it up, there may be distribution challenges in the region but manufacturing JVs can prove to be the way out as Ukraine, Uzbekistan and Russia are in favour of manufacturing JVs. If manufacturing facilities as set up in Russia or Ukraine any other markets in that belt could be catered to.

This content is based on the thoughts shared by Mr Anant Pandya during his talk on 'Strategies for CIS Countries' at Pharmexcil Seminar on 'Overseas Marketing Strategies' in Sept'13.

Mr. Anant Pandya is Director at Zandra Lifesciences Pvt. Ltd. He has an extensive experience in overseas marketing domain especially in the CIS countries.

Should pharma players keep an eye on the burgeoning African market?

Market Scenario & Product Dynamics – Africa is a land of great opportunities with about 54 countries. The continent has a population of over 1 billion which is almost 15% of the world's entire population. It is note-worthy that almost 60-80% of the Pharma demand market is imported and it can be an opportunity for any Pharma company. The Pharmaceutical market in the African region is estimated to be about USD 10 billion.

Also, there is a large presence of Indian, Chinese and multi-national companies in the African market and Chinese companies, especially, are making their presence felt in a big way. The problem with this market is that it is a very basic one, not too sophisticated. Paracetamol, Aspirin, etc. are seen in plenty but now lifestyle products are being made available in the anti-diabetic, cardiac and anti-obesity markets. This is majorly due to the changing lifestyle as well as the changing economics of the continent. A typical product basket in an African market would have analgesic, anti-pyretic, rheumatic products at 25%, antibiotic-antimalarial 15%, multi-vitamins & hematinics 15%, anti-hypertensives 8%, cough and cold 5%, external topical preparation 5%, anti-TB 4% and others at 3%. Anti-retroviral is also a big opportunity in countries like Nigeria & South Africa. Hematinics are also an interesting product segment.

Distribution in the African Countries – Africa can be divided into two separate blocks when it comes to distribution, Anglophone countries and Francophone countries. The distribution channels in the Anglophone and Francophone countries are totally different. In case of Anglophone countries such as Nigeria, Ghana, Uganda, Tanzania, Kenya, Zambia or Zimbabwe, there are unlimited distributors in the market. But in the Francophone countries, there are only three to four distributors. In the Anglophone countries, the distributor has the job of distribution which includes the logistics collection of your sales values. But in the Francophone countries, the role of the distributor is only to distribute, be a wholesaler. The distributor just accepts the goods and distributes them based on the orders that are generated by the agent of the manufacturer. So, it is up to the manufacturer to appoint an agent for them in a Francophone country.

Pricing and Payment Terms – There is tough competition from the overseas principles in the Anglophone countries; the prices are not controlled here so they have to be changed constantly. On the other hand, in Francophone countries when registering a product, a PGHT price has to be set. PGHT is the price at which the product would be sold and it is exclusive of taxes. The PGHT price once registered cannot be changed at will; it can be changed only up to 5% after 2-3 years. Payments range from LC, Advance or DA terms. With the influx of many Indian companies, companies have to agree to DA terms of 90-120 days.

Pharma Market Opportunities – There are many opportunities that aspiring Indian pharma companies can exploit in the Anglophone and Francophone countries. An alternative way of entering the Francophone country is by appointing French distributors. There are large distribution companies located in France such as Plant Pharma, Urimax, etc. This was a good option for companies who did not want to experience any marketing hassles in a region where even language was a barrier and these companies served as their agent. But, these companies have started getting contract manufacturing done from India and China under their own brands more recently. Also, Francophone countries have negligible local manufacturing being done there if compared to Anglophone countries. There would only be one or two companies doing business there and almost 85%-90% of the country's demands are taken care of through imports. Anglophone countries are a little more sophisticated and advanced in comparison. Regulations and Registrations – In both Anglophone and Francophone countries, there is a list of products that are restricted for imports. In Nigeria, about 17 products are restricted in the list for imports. The reason for this is that the local companies can suffice the need of the demand of those products; mostly basic ones like Paracetamol, etc. In most countries across Africa today, the regulatory authorities, the level of sophistication, resources, vary greatly. The common factor here would be that most of the countries wish to follow the CTD (the common technical document) under the WHO and

ICH guidelines. The general dossier that an Indian company would make for its product would be almost 90% FDA compliant with most of the requirements there. Just in case of Francophone countries, the dossier would have to be in French because they do not accept it in English. Also, the site master files are mandatory. Most Anglophone countries want to have a plant audit; the cost of this audit varies from one country to another and can vary from USD 2,000 to even USD 10,000 or more depending on the country.

Regional Associations – There are a number of associations within the African region. The East African community (EAC) comprises of Uganda, Kenya, Tanzania and Rwanda which are trying to form an economic block. The Economic Community of Western African States (ECOWAS) comprises of 15 countries that want to form a political & economic block; some countries are Nigeria, Senegal, Sierra Leone, Ghana, Benin, etc. Another organisation is COMESA which has 19 member countries like Egypt, Libya, Ethiopia, Zimbabwe, Zambia, Sudan, etc. All these regional blocks are trying to harmonise the registration and regulatory authority such that in the future if you register in Nigeria, the same registration would hold good for the fifteen ECOWAS countries. But this would take some time still. Thus, the cost of registration is high as individual products have to be registered in each country separately.

South African Market – South Africa is the most sophisticated market; it is the largest market in the African region. In 2012, the estimated market size of this market is 3.84 billion dollars. This market has seen a great and rapid change in the last two decades. In the apartheid regime, mostly multi-national patented molecules in generics were allowed in the country. But, this has begun to change in the past two decades with the new Government's efforts. The Government wants to expand the healthcare to a lot of people; they want to bring in more generics. With regards to generics, the price can be much more competitive so it is possible to extend the healthcare expenditure. Currently, the generics market stands at 30% of the total sales at USD 1.12 billion. It is estimated to grow to 2.23 billion by 2017 which would be almost 100% in the next 3 years. The patented market today accounts for almost 64% which is about 2 billion dollars. With the new Government policies being introduced, the generic drugs are expected to grow. South Africa used to follow Intellectual Property (IP) very stringently. But, the Government has realised that if they wish to take advantage of generics, they would need to change their IP laws. So, now they are changing them to gain access to cost-effective generics with compulsory licensing and voluntary licensing. But, this would still take a year or two to be implemented. The registration fees in South Africa are generally USD 1,750 and it takes anywhere between 1-3 years for registration. It should be noted that the country has the most developed local production in Africa with a very large volume of sophisticated drugs. But quite a large volume of drugs is still being imported. The imports are done mainly from India, US, Germany, Italy and France and the value of imports in 2012 was almost, 2.2 billion dollars and is likely to increase to 3.47 billion by 2017. But considering the complete market scenario, South Africa is still a private market. A large majority of the population does not have access to proper healthcare. So, the government is putting efforts into have a National Health Insurance in place which is supposed to cover the entire population.

Conclusion – On primary level, Africa is a trading continent. The pharma market is still growing and has good business potential for Indian manufacturers. One important factor to be considered is to have a distributor or agent who is dynamic, trust worthy; it would be wise to do a thorough research to find out how good a distributor or agent is prior to an alliance. It would be in a company's favour to consider some of the African countries in their strategy plans for the future.

This content is based on the thoughts shared by Mr Kaustubh Dharkar during his talk on 'Strategies for Marketing Formulations in African Countries' at Pharmexcil Seminar on 'Overseas Marketing Strategies' in Sept'13.

Mr. Kaustubh Dharkar has a wealth of experience in various facets of the pharmaceutical industry. He has had an illustrious career where he has held several high level positions - be it COO, CEO, MD & more. With a very strong and wide exposure to the African pharmaceutical market for about 13 years, he has worked in East-West as well as Southern Africa..



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