Vol.15 Issue-1, 2016-17

INTERLINK INSIGHT
Perspective for business performance

AN ESSENCE
OF STABILITY & GROWTH

FROM THE PUBLISHER'S DESK

'An Essence of Stability & Growth'

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

Can growth and stability co-exist?

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

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

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

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

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

Hope this **Interlink Insight** issue makes a worthy reading.

On your feedback we thrive.

Wish you the best of reading!

Yours Sincerely,

Dr. R. B. Smarta
Managing Director

Publisher - Dr. R. B. Smarta
Editorial Team - Mr. N. Sanglikar
Ms. Shreya Pathare
Ms. Ankita Dhekne
Mr. Rajkumar Natekar

Interlink Marketing Consultancy Pvt. Ltd.
3A, Central Plaza, 166, C.S.T. Road, Kalina,
Santacruz (E), Mumbai - 400 098, India.
Tel.: (022) 2666 6611 / 44
Email : info@interlinkconsultancy.com
Website : www.interlinkconsultancy.com

CONTENTS

An Essence of Stability & Growth:

Managing and growing mature brands are the challenges faced by many organizations. But it is also important to identify and know whether all brands are worth reviving. Read the article to get insights on what exactly are mature brands and to know about the strategic options to revitalize these mature brands as discussed in an inclusive way by Dr. R. B. Smarta.

AN ESSENCE OF STABILITY & GROWTH: MATURE BRANDS

90% of the pharmaceutical market is captured by heritage brands. Having stated that, managing and growing mature brands are the challenges faced by several organizations. Before addressing the challenges, it is important to answer one key question, 'are all brands worth reviving?' What are the brands that the organization should attempt to grow and what others should be allowed to die or divest?

Mature Brands

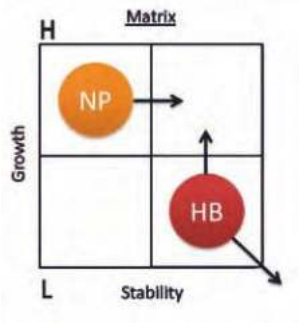

Fig. a

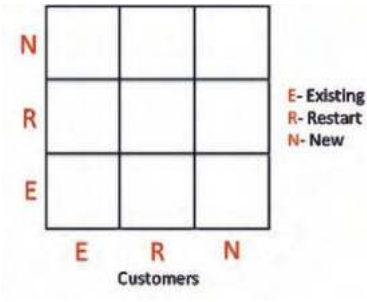

Fig. b

Mature brands, also termed as heritage brands, are very often considered as efficacious and a gold standard in a particular therapeutic area, with a bonus of a predictable safety profile. These brands are also cost-effective for the customers, profit generators for the organization and capture a market size that cannot be ignored by the organizations. Irrespective of the positive points, there are certain challenges faced by the mature brands. Heritage brands have low growth but high stability (Fig. a). These heritage brands have the possibility of either attaining higher growth or withering away. Revitalizing these brands can strengthen the bottom lines and bring stability to the organization.

Brands too have a life-cycle and they either live or die. Certain brands suffer death from obsolescence or due to the changing technology, research, efficacy, etc. These brands can be then rejuvenated with new products and services. However, well managed brands which deliver good results can prosper for a long time. Research shows that existing brands in the market years ago are still in the same position. Research also shows that it has been proved difficult for a new brand to overtake these existing leading brands (Fig. b). This means that they have the ability to extend the life cycle or, possibly, the effective marketing of these brands has meant that the life cycle, in its purest form, does not exist.

By applying well-conceived strategies, a brand can prove relevant to consumers, can provide long term consumer value and can last for almost time infinity. This concept can be well justified by the stories of Barbie, Colgate, Coca-Cola, Marlboro, Mercedes-Benz, Nescafe and Kodak, to name a few. We have brands like Liv-52, Benadryl, Aten, Beplex Forte, Unizyme, Heptaglobin among others that are still living on. Time has shown that even with the change of therapies, mature brands remain evergreen withstanding the test of time.

Mature brands have a brand heritage associated with them. This brand heritage voices its status, character, social class and history. Brands that are still alive and have a strong brand recall in spite of all the odds are truly classified under heritage brands. These brands in turn leave a strong image in the minds of their consumers. These brands need not necessarily be a product, but can be anything- a University (IIM, Harvard), a movie (Sholay) or a person (Mr. Amitabh Bachchan). Thus, building a mature brand involves clear positioning, legal protection along with imaginative expressions of the brand's identity. The brand's heritage is the single most characteristic or attribute that provides the mature brand its sustainable competitive advantage.

Mature Brands Pose Challenges

Mature or heritage brands come with a string of challenges as well. As the brand ages with time, the number of competitors increases. The brand is likely to supersede therapeutically and either have a flat or declining sales trend. Immediate challenge would be the imminent or already available generic products. Also, the in-house product expertise is likely to decline with little or no sales force activity. Additionally, the Doctors are likely to be unresponsive to the brand since they would have 'heard it all before'.

A once-strong brand becoming obscure is another challenge. This obscurity is due to the brand managers losing sight of the customer and attacking the competition instead. The mounting pressure for profit leads some organizations to shift their focus to competitors at the cost of the consumer. In this scenario, the organizations have the option of either fighting the competition or shoring up the consumer's loyalty or identifying new uses for the brand and in turn generating new consumers.

Reasons for Brand Maturity

Competition

Competition in terms of new superior molecule in the same category or new research on diseases keep changing the guidelines for diagnosis and prescription. A classic example would be Asthma, where the treatment has undergone changes multiple times with respect to new research and molecules. In this environment, if the mature brands have to grow then there needs to be methods devised to ward off the threats due to the newer impending molecules. In some cases, competition is not just from other drugs or molecules, but from physical interventions. For example, treatment for atherosclerosis have to compete with angioplasty or toothpastes for sensitive teeth have to compete with root canal treatments.

Stagnating Category Sales

If the entire category is declining, then a brand from several brands in the same category may use rejuvenation techniques. It makes absolute sense to build your brand at this time since this is the time when ambience is clutter-free and when the message gets communicated to the prospect clearly.

Loss of Differentiation

A brand might need revitalization if it has lost its USP or if the earlier points of product differentiation have been diluted by copy-cats. The basic idea in this case would be to rebuild the brand from scratch so that it could still communicate advantages over the competition.

Aging Target Market

Another reason which calls for brand rejuvenation could be change in the age-profile of the target market of the brand. This renews the position of the brand in the minds of the next generation consumers. For instance, enzymes used to be prescribed by doctors freely. However, the trend nowadays is to prescribe natural products which threaten the older enzymes brands.

Changing Consumer Needs

Changing environment has led the consumer to demand for better, more efficacious products. The brand may thus, need revitalization if it no longer meets the prescribers' or consumers' needs.

Are All Old Brands Worth Revitalizing?

Marketing mature brands is more often a case of managing the decline and delaying the inevitable. The challenge is to secure in-house resources in terms of promotional budget with sales force commitment often being out of the question. It is, therefore, vital to decide which brands are worth reviving. The companies, which own these brands, have four options: (1) Revitalize them (2) Milk them (3) Sell them (4) Prune them.

It is extremely important to consider all the aspects before finally deciding on revitalizing mature brands. Some of these aspects include significance to the organization and heritage of the brand. Another deciding aspect would be whether the brand is at growth maturity, stable maturity or decline maturity.

A Rainbow Approach for Mature Brand Revitalization

The organization needs to consider various strategic options once it decides to revive a brand. It goes without saying that the direction that a brand would take depends on insights of the consumer, a fact-based assessment of the brand's identity and its legacy. Identification of critical growth drivers and quantification of each growth driver is the key. For this purpose, we have developed a rainbow approach for revitalizing mature brands.

Fig. a. Rainbow Approach for Mature Brand Revitalization

Source: Interlink Knowledge Cell

How can these brands move from classic old school to new school? There is no sure shot way; however, there are some key guidelines to help.

1. Product Innovation

'Discontinuation Innovation' is the way through which marketers can reverse the decline of brands and markets. This is a development that fundamentally alters the state and perception of a sector. For instance, tea bags revolutionized the way tea was perceived, thus, ending the ritual of pouring tea from a pot and turning it to a fast turnover convenience drink.It is critical to connect with the consumers and also find new ways of connection by bringing about changes and innovation in ways they experience one's brand. This further involves rethinking the product, customer service level along with channel strategies.

2. Growth in Emerging Markets

Emerging markets provide tremendous opportunities for mature brands and products. The more technologically advanced the product, the shorter its period of rapid growth, and the longer its era of flat sales and eventual stagnation. There is little growth in sales of televisions, though innovation during the eighties kept the market buoyant. There is a replacement cycle, rather than growth in penetration, people generally buy the latest flat screen TVs when they are looking for a new set. Most mature pharma brands have failed to penetrate the vast rural market. Reaching doctors and patients is a challenge that needs to be addressed as the brand pierces though the customer segments.

3. Going Back to Brand Legacy

The history associated with heritage brands is what differentiates it from the others. The trick lies in identifying that magic and working on it. Nostalgia can act as a key pull factor to draw consumers back to the brand they once loved. However, this cannot be applied to all heritage brands. Thus, it is necessary to explore the equity of each heritage brand thoroughly. The key here is to capitalize on the existing brand strength and also to make sure that the good isn't thrown out with the bad. Lack of new scientific papers nationally and internationally is the challenge faced by many Pharmaceutical brands. There are constant queries from our client companies to generate medical data through meta-analysis or articles that would provide new material of interest to the Doctors. In some of our consulting assignments for brand strategy, it has been the brand legacy that has come to the rescue of the brand – the case in point being Nitravet, where the legacy of the brand and the brand promise were highlighted leading to revival of the brand.

4. Finding Your Audience Again

It is very important to find your niche with the younger, trendier segments of the society especially if you are in a more forward looking, research driven industry like Pharmaceuticals. Each brand is different and how far to stretch the audience beyond the traditional consumer base will entirely depend on the industry, brand legacy and also how well the needs of the younger consumer segments can be met by the brand.

5. Being Relevant Again

Many of the heritage brands have fallen out of fashion. Reasons for this include products no longer used in modern times, emergence of new brands or solution alternatives and brand image not catching up with current times. This has led to many heritage brands losing their relevance with consumers today.

6. Playing Up the Legend

Every brand has a story and it is this story that helps us understand and identify with the brand with respect to what it is, where it comes from, what it means to buy from it and what it means to work from it. This story is, thus, a powerful way to revive mature brands. However, many heritage brands either tell their story badly or dwell too much on past glories and alienate potential new customers. The story of the brand should be weaved and told in a way and context of how it helps deliver its promise. This in turn helps establish credibility and win more audiences.

7. Outsource

Managing mature brands can be quite a task at times especially when the organization has other priorities like establishing a range of new products or growing the portfolio of large brands. Our experience also shows that most brand managers tend to work on therapy areas that are current and futuristic due to which the older brands take a backseat. Also, mature brands tend to end up just as lame reminders to doctors since there is a crunch on the number of brands promoted to them. Thus, mature brands often languish with little time, money and attention, all from product management and field force. In this scenario, it is best to outsource the management of brand to an external agency for both sales and marketing.

Another option would be to get an external perspective like that of a consulting firm in order to develop and support the implementation of brand strategy. This will, in turn, offer a fresh look to the brand and also build commitment towards brand management leading to the success of the brand.

Conclusion

Mature brands are the heritage of any organization. Revitalizing these mature brands can improve the bottom lines of an organization. Also, brands have the potential to live longer. While bad brands may fade away, good brands though, should never go.

About the Author

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

Special Feature

Is it the Right Time to Engage Patients?

Recent years in the pharmaceutical industry has seen an increased focus on patients. Many pharmaceutical companies are becoming patient centric rather than being business centric. Read on to know whether the it is the right time to engage patients as discussed in an inclusive way by Interlink Knowledge Cell.

IS IT THE RIGHT TIME TO ENGAGE PATIENTS?

Over the recent years, there has been a shift in focus on patients. Pharmaceutical companies are becoming patient-centric apart from being business-centric and therapy-centric. Additionally, patients are turning more active in updating their knowledge and skills to manage their own health which is commonly termed as 'patient activation'. Patient activation plus interventions are what make patient engagement a widespread concept. The IOM (Institute of Medicine) defines patient-centered care as: "*Providing care that is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions.*"

Patient-centered care is also one of the outplaying goals of health advocacy, in addition to safer medical systems, and greater patient involvement in healthcare delivery and design. Patient-centricity or patient delights are not just new words but imperatives whose time has come.

As quoted by Jack Barette, WEGO Health, **"If patient engagement were a drug, it would be the blockbuster drug of the century."**Patient-centricity basically means active participation of patients and their families in the design of innovative care structures. Improving the lives of patients and keeping the patient at the center is the true meaning of patient-centricity. Patient engagement or patient activation is simply the application of patient-centered care.

Sanofi had created a Partner in Patient Care advocacy group that viewed the patient as a principal source of insight and a partner in engagement.

Pharmaceutical companies have an opportunity to change people's lives by supporting, connecting and helping them manage the changing healthcare backdrop. There is an urgent need for pharmaceutical companies to not consider patients as the end-result and realize that the patients need help and that they have the resources to assist them.

Patient Centricity in India

All this while healthcare in India remained 'physician/ hospital centric'. The patient had to run from pillar to pillar to seek correct treatment. The use of complicated therapeutic technologies has generated a need for centralized-care delivery system. Increasing chronic disease burden and poor health indicators in India have pressed the need to influence patient behaviors to improve health outcomes. There is a huge gap between demand and supply for quality healthcare in India. Thus, achieving patient-centricity will not come easily in India, but it is feasible by implementing grassroot efforts. Winds of change have been sweeping the urban areas with respect to patient-centricity with only a few corporate hospitals thinking in terms of creating delightful experience for their customers.

Five Ways to Achieve Patient Centricity

Patients expect more services from the pharmaceutical companies along with their products. According to a study conducted, 76% of patients expected something more from the pharmaceutical companies.The patients are of the understanding

now that the industry is the best source of information about its own products along with knowing that there is essential value attached to it. Value-oriented model, offering development and value-delivery, will help pharma companies accomplish patient-centricity.

1. Retail pharmacy is slowly growing and the number is expected to double in the coming few years. They are filling the critical gap in the system and are making medicines more accessible and affordable. To sum it all up, pharmacies are the perfect place for patient engagement.

2. Patient engagement can also be achieved with healthcare extenders. Healthcare extenders are those professionals that work in a traditional healthcare environment. Healthcare extenders are the unsung brand champions. They work directly with patients and thus, understand patients with respect to medical adherence.

Fig.a 5 Ways of Achieving Patient-Centricity

Source: Interlink Knowledge Cell

3. True patient engagement can help screen different types of disturbances of the patients. A study revealed that the healthcare environment is largely fragmented. It also revealed that the patients were staying engaged and finding their own work-around solutions despite feeling frustrated with the system. Thus, the pharma companies have plenty of scope and opportunity to help make the patient's Do It Yourself experience easier. Social media can truly help pharma companies in patient engagement. Social media is often used by pharma companies to promote its real-world engagement with patients. Over half of pharmaceutical executives list grasping multi-channel marketing and improving digital effectiveness within their top strategic priorities. Social media can be used as a channel to provide "pastoral support" to patients efficiently. A well-established social media presence can provide an important forum for patient engagement. One of the key areas of patient dissatisfaction is a lack of any sort of acknowledgement when they share an experience or their needs. A well-established social media presence not only

provides a forum for patient engagement, but also allows for crowd-sourcing ideas and feedback.

4. By capturing both on and off-treatment experiences, pharma companies would be able to understand patient emotions and frustrations that can influence outcomes.

5. Integrated value chain strategy that is centered on providing solutions to patients will be effectively useful for patient-centricity.

Challenges Faced

Patient-centricity is not easy, but it is feasible. Some of the challenges faced by Pharma companies were identified as follows:

1. A shift from Product-centric culture, as it exists currently
2. Primary focus on relationships with the physicians
3. Assumptions about regulatory barriers
4. Insufficient priority given to patient-centricity projects
5. Lack of long-term focus
6. Lack of global strategies
7. Lack of support from internal decision-makers
8. Lack of convergence between patient-centricity and business

Conclusion

Patient-centricity requires a universal change. It demands alignment and intensive efforts of the most powerful stakeholders. When implemented correctly, patient centricity can have a noteworthy impact. Efforts include recognizing how multiple stakeholders influence the patient experience, mapping the entire patient journey and using strong leadership practices to keep everyone in the organization focused on the same goals. The ultimate goal is a better quality of care for all and access to services extended to everyone including people with special problems and people living in underdeveloped or emerging countries.

Interlink Knowledge Cell

Interlink Knowledge Cell comprises of a team of experienced subject matter experts in various domains like Pharmaceutical, Nutraceutical, Biotechnology, Animal Health and Wellness, to provide insights and business perspectives focused on Management, Marketing, Sales & Training areas.

Connecting Dots: Make in India to Made in India

Make in India initiative was launched to give a boost to the Indian economy. The Indian pharmaceutical industry is at the forefront of this initiative. Read on to know how we can connect the dots for taking the initiative from Make in India to Made in India as discussed in an inclusive way by Dr. R. B. Smarta.

CONNECTING DOTS: MAKE IN INDIA TO MADE IN INDIA

One of the most transformational initiatives to boost India's economic growth in the coming years is the Make in India campaign launched by the Our Hon'ble Prime Minister, Mr. Narendra Modi, on 25th September, 2014.
This initiative was launched to give a boost to Indian economy i.e. to shore up investments, infrastructure development, employment generation as well as financial inclusion in the country.

Progressive thoughts like liberalization of foreign investments would allow organizations to raise long term capital at competitive prices and would immensely augment the dual agenda of 'Invest in India' and 'Make in India', making India a global manufacturing hub of excellence. It would also result in more job opportunities for the youth of India.

Considering the whole **'Make in India'** scenario, Indian pharmaceutical industry is at the lead of the initiative. India's need for medicines is majorly satiated by drugs manufactured domestically. The pharmaceutical sector has come a long way, from import-dependence before the 1970s to today where India is acknowledged for a deep knowledge base in pharmaceuticals that differentiates it from other low-cost suppliers of pharmaceuticals. India's pharmaceutical industry has been growing rapidly, nearly doubling in the last five years.

In this scenario it is important to answer how we can take the Indian pharmaceutical industry to the next level of growth? What are the advantages and concerns in front of us? How do we tackle them?

Global Pharmaceutical Dynamics

The global pharmaceutical market is worth USD 300 billion per annum, which is expected to grow to USD 400 billion within next 3 years. One-third of this market is controlled by the 10 largest drug companies, many with sales more than USD 10 billion per year and profit margins of about 30 per cent.

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

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

In pharmerging markets, improved access and strengthening economies would

drive higher demand, particularly for generics.

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

R&D Intensive Business Model

Inside-Out Innovation

The R&D intensive nature of the industry is changing due to a fall in the return on R&D investments in the last 20 years. This is the reason why investors are attributing less value to the drug companies' product pipeline. As a result, the business model that empowered the pharmaceutical industry over the last few decades is showing signs of lassitude.

People all over the world, in current times, are looking for not only treatment but also health solutions that will keep them healthy in the long run.

The industry thus, needs to switch over from being product-orientated to a more service-oriented model. The needs of the patients and the patient ought to be at the heart of the model with the business services wrapped around them.

Outside-In Innovation

Adopting the patient centric or the total care model will not only lead to new revenues but also to the development of new, innovative products due to better understanding of medical conditions.

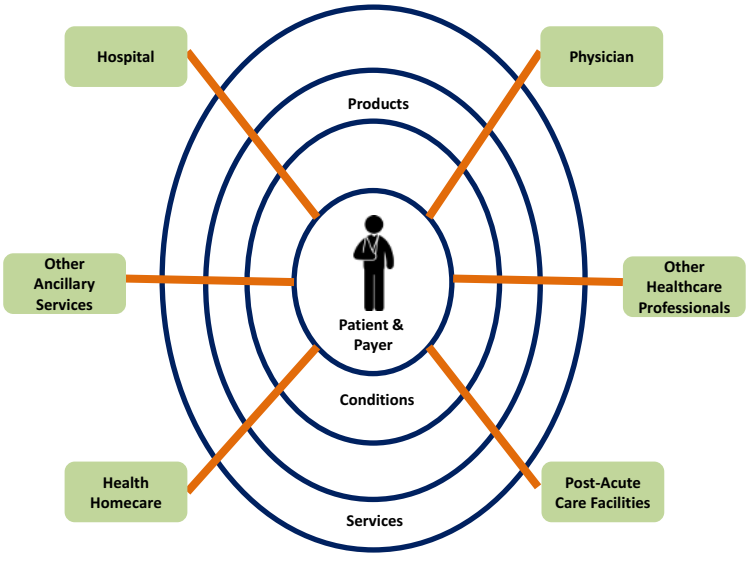

Fig. a, Total Care Model

Source: Interlink Knowledge Cell

The world is experiencing a shift in the way medical care is delivered. In other words, it can be said that healthcare is evolving. There is improved understanding of the disease by the patients, thus, enabling them to be better aware of the treatment provided to them. The industry is working closely with the Government, regulators and the healthcare community for an effective care system thus, providing a holistic healthcare service. The industry is also tailoring its sales, marketing and pricing strategies for better accessibility and affordability to the patients. The industry is making sure of going 'beyond the pill' by extending additional services to the benefit of the patients. The focus of the industry now is on patient centricity and patient engagement.

In order to capitalize on its potential, the pharmaceutical industry needs to **innovate new business models** and find ways to **collaborate across healthcare ecosystems**, all the while by **keeping patients at the epicenter.**

Indian Pharmaceutical Space

The Indian pharmaceutical industry is globally respected and is one of the most successful industries in India. The Indian pharmaceutical industry has achieved an eminent global position in the pharmaceutical sector and has been witnessing phenomenal growth in recent years. This has in turn contributed immensely to India's healthcare outcomes and economy. In addition to helping ensure affordable and accessible medicines in the far reaches of India, it has also generated employment, directly or indirectly engaging around 2.5 million people.

The industry has nearly doubled in the last five years. The Indian pharmaceutical market was valued at INR96954crores in January 2016. Indian pharmaceutical sector is the third largest in terms of volume and thirteenth largest in terms of value in the world. Much of this growth is due to rapid growth in exports—India's pharmaceutical sector is the fourth-largest exporter of goods in India.

Contract Research and Manufacturing Services (CRAMS) and the Biotechnology industry emerged as the two fast growing segments in the sector. India is among the top 12 biotechnology destinations in the world and ranks second in Asia, after China.

India is emerging as a world leader in generic pharmaceutical production, catering to 20% of the global supply of generic medicines. The industry accounts for 8% of global production, and exports to over 200 countries. It is estimated that Indian generics will be valued at USD 26.1 billion by 2016.

India is a major vaccine producer and has 18 major vaccine manufacturing facilities. These vaccines are used for the national and international markets (150 countries) which make India a major vaccine supplier across the globe.

World-class capabilities and market conditions ensure that India continues to be one of the most lucrative pharmaceutical markets in the world.

Heading Towards Enormous Growth

The Indian pharmaceutical space has a plethora of advantages to leverage on

along with its share of concerns to tackle in order to head towards the projected enormous growth at the global pharmaceutical platform.

Advantage India

1. High Incremental Growth

India is expected to rank amongst the top three pharmaceutical markets in terms of incremental growth by 2020. Globally, India is all set to become the sixth largest market in terms of absolute size by zero.

2. Patient Pool

Rise in India's population is expected to increase its patient pool to over 20% in the next 10 years. Additionally, the supposed rise of lifestyle diseases in India is expected to boost industry sales figures.

3. Generics

The country is the largest provider of generic medicines worldwide accounting for 20% of global exports in terms of volume. The affordability for generic drugs in the market is also likely to improve with improvement in economic prosperity. It has been estimated that between 2011 and 2016, patented drugs worth USD 255 billion will go off-patent leading to a tremendous surge in their generic equivalents. The generics market is expected to grow to USD 11 billion by 2020 at a CAGR of 18% with a potential to reach USD 13 billion at an aggressive CAGR of 20%.

4. APIs

Bulk drugs include the Active Pharmaceutical ingredients (APIs) which are used for the manufacture of formulations. According to estimates, the proportion of formulations and bulk drugs is 75:25. There are believed to be over 60,000 formulations manufactured in India in more than 60 therapeutic segments. More than 85% of the formulations produced are sold in the domestic market.

5. Growing Exports

India exports pharmaceutical products, APIs and intermediates to more than 200 countries across the world. The proportion of exports in domestic turnover has been increasing remarkably over the years, despite the growing domestic demand.

6. Expanded Presence in Regulated Markets

Over the years, India has shown better regulatory awareness and superior technical skills, which has enabled Indian companies to penetrate the high-value markets like US and EU. Regulated markets, though difficult to penetrate due to stringent regulations, are known to give better value and margin to exports.

7. Increased Hospital Share

Pharma companies have increased spending to tap rural markets and develop better infrastructure. As a result, the market share of hospitals is expected to increase from 13.1% in 2009 to 26% in 2020.

8. Low Cost Production

The cost of production in India is significantly lower than that of USA and is half of that of Europe giving it a unique advantage over the rest of the markets.

9. Less Approval Time
The approval time has been drastically reduced for setting up new facilities in the Indian market.

10. Skilled Manpower
India has a bandwagon of highly skilled labor along with high quality of managerial and technical competence.

11. Affordability & Accessibility:
The affordability and accessibility of modern medicine and newer therapies would increase due to aggressive market creation by players. The contribution of growth drivers would undergo a shift. Together, these two factors will account for nearly 70 per cent of the incremental USD 42 billion market opportunity. Increased acceptability will account for another 25 per cent.

Concern India
1. High Level of Commoditization
High levels of commoditization is a growing concern for Indian pharmaceuticals with portfolio of products getting commoditized with high competition at the product or SKU level. Moreover, proliferation of SKUs/products have made supply chains increasingly complex, further affecting productivity and costs.

2. Growing Dependence on External Markets
There is growing dependence on external markets for raw materials. The sector continues to rely on imports of key starting materials, intermediates and APIs; with the share of dependence increasing over time. This dependence impacts supply chain flexibility and control cost for formulation manufacturers.

3. Increasing Customer Consolidation
Another growing concern is that customers in developed markets have consolidated at a rapid pace, in turn increasing pressure on prices. Additionally pricing regulations on products and many more markets have put further pressure on margins.

4. Competition
The Indian pharmaceutical sector is facing increasing global competition from its global counterparts. For instance, the Chinese players are expanding downstream, from APIs to formulations. Of the top 15 Chinese players in API, 14 are now present in formulations. Also, there is intense competition in complex generics and new technology. Countries like China and South Korea have had many more approvals and evolved manufacturing capability for complex molecules and new technology. To gain competitive advantage in this space, India must invest in developing or acquiring the desired set of capabilities including R&D and manufacturing. However, these investments could result in substantial increase in per unit costs in the short term.

5. Regulatory & Policy Concerns
Regulators such as USFDA are focusing on improving fundamental quality systems and procedures across the enterprise rather than addressing individual site-level observations.

Over the last five years, a lot of initiatives have been taken by the government to boost the Indian pharmaceutical industry. While some of these policies have progressed in the right direction, there is scope to accelerate implementation for some of them and fine-tune others/ based on feedback from the industry.

While a lot of good policies are in pipeline, if not executed on time would lead to high opportunity cost.

There are areas where regulators, government and industry have had different opinions and managing them well is critical for industry growth.

Connecting Dots for Make in India to Made in India

Both nationally and internationally, Indian pharmaceutical industry can contribute to health economy outcomes in big ways. This would however, need collective efforts and actions from all the stakeholders of the industry. The Patient Centric Revenue Model thus, can be leveraged to effectively drive the growth of the Indian pharmaceutical sector during the **'Make in India'** era to ultimately achieve the ambition of **'Made in India.'**

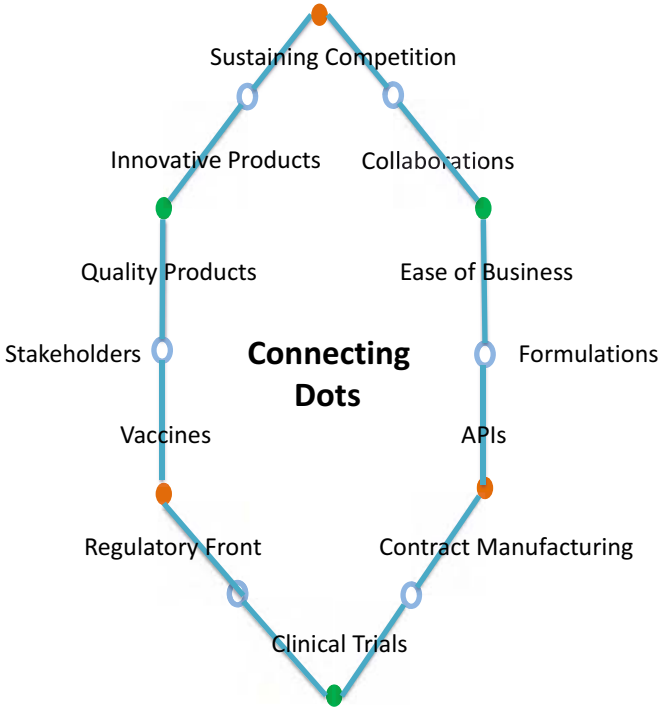

Fig. b. Connecting Dots for Make in India to Made in India

Source: Interlink Knowledge Cell

1. Focusing on Quality of Products to Maintain the Sector's Image

In order to maintain Indian pharmaceutical's image and its global market position, it is important to focus on the quality of products. It is important for the organizations to upgrade quality systems, infrastructure and also enhance capabilities of India in order to be recognized as a high-quality supplier. The organizations need to approach a four pronged holistic approach to fundamentally transform the quality systems in the areas of Systems & Processes, Organizational Capabilities, Management & Metrics and Mindsets & Behaviors.

2. **Innovative Product Launches for Driving Growth**

Innovation can effectively drive the growth and success of the Make in India campaign for the Indian pharmaceutical sector. The key lies in building a globally recognized position for India through an enterprise-driven approach.

3. **Sustaining Competition for Advantage India**

Low production cost and fast speed to market are the advantages of Indian pharmaceutical market that face the threat of growing global competition. In order to sustain this competition, it is necessary for players in the sector to build up new sets of capabilities by exploring and adopting new technologies, improving compliance, reviewing and optimizing processes, and scaling and building global leadership in volumes for a range of selected products.

4. **Collaborations for Industry Evolution**

Meaningful collaborations within the industry would support the growth and evolution of the industry. Increased collaborations are the key to address the growing scale of challenges within the market and for moving forward.

5. **Facilitating Ease of Doing Business**

There is a need to strengthen the current business environment and also facilitate ease of doing business within the industry. This could be achieved through the Government's support by maintaining the industry's cost leadership in the global market, export incentives, easier duty structures, concentrated pharmaceutical parks/ cities, etc. Also, the Government should encourage new players for setting up new facilities in the sector. Through its initiative 'Invest in India', the Government can reach out to potential investors and promote the Indian pharma space.

6. **Sustained Growth for Formulations Manufacturing**

The manufacturing cost in India is 65% lower than the US and 50% lower than Europe. India produces 60,000 generic brands across 60 therapeutic categories and also manufactures more than 500 different APIs. India has over 120 USFDA approved and 84 UK MHRA approved manufacturing facilities. As per 'Pharma Vision 2020', the Indian Government aims at making India a global leader in end-to-end drug manufacture. Indian pharmaceutical industry can aspire to deepen its presence in global markets as well as build a stronger presence in key emerging markets to create a platform for sustained growth in formulations manufacturing.

7. **Self-Sufficiency of APIs**

Given the increasing competition from China, through joint interactions, the Government should identify strategic priorities and in turn provide a holistic

support. One of these is to ensure India's self-sufficiency by helping enhance competitiveness of the local API industry. Ensuring India's self-sufficiency in API/intermediates will be critical to maintain the competitiveness of Indian players and to ensure supply security for the local market. The government could explore setting up three to five dedicated clusters across the country for the API/ intermediate industry. Investing in next-generation APIs can help the Indian industry to be at the forefront of these technologies and differentiate itself from other players.

8. **Indigenous Vaccines Manufacturing**
India has scope and demand for indigenous vaccines, both existing and new players can capture this opportunity in vaccines manufacturing.

9. **Contract Manufacturing**
With increasing pressures on managing costs and shortening time to market globally, Indian Contract Research and Manufacturing Services (CRAMS) companies have an opportunity to be viewed as strategic partners to global pharma companies rather than transactional suppliers.

10. **Hub for Clinical Trials**
Due to its cost advantage, India is increasingly becoming a hub for clinical trials. Due to a genetically-diverse population and availability of skilled doctors, India has the potential to attract huge investments to its clinical trial market.

11. **Regulatory Front**
In current times, India is perceived as one of the most affordable and accessible pharmaceutical markets. Having a regulation regime that is transparent and predictable would help facilitate the ease of doing business and would also attract further investment in the sector while safeguarding needs and interests of all stakeholders.

FDA has announced a shift towards guidelines laid out by the WHO. To ensure consistency with the global standards and maintain the thrust on quality, it is important to periodically review these guidelines.

To build an enabling regulatory environment in India, the regulators could consider providing further clarity on regulatory requirements in a few areas like comprehensible guidelines for clinical trials, criteria for evaluation for approval, etc.

12. **Role of Other Stakeholders**
Healthcare professionals should proactively participate and shape development of new medicines. Forums of healthcare professionals can also continue to play a significant role in shaping the healthcare policies of the country. Academia can also play a major role in fostering research in collaboration with the industry. There is a need to create forums that can improve transparency and collaboration between academia and the industry.

Leveraging Further Advantage for Make in India

To head towards the enormous growth in the global pharmaceutical platform, it is extremely essential and at the same time crucial to leverage **Advantage India** and simultaneously work on **Concern India** in the pharmaceutical space.

To further realize the dream of achieving the ambition of **Made in India**, the Indian pharma needs to further leverage the advantages of Indian pharmaceutical space to the likes of the integrated platforms. An integrated platform is evolving and the patients are in need of such integrated platforms. This platform needs to be based on two essential building blocks, transferring formulations R&D to manufacturing and linking patients' feedback to manufacturing thus, helping the patients and the customers in the long run to stay healthy.

Also, with rising awareness about wellness, shifting trends in the pharmaceutical industry and with people opting for treatments with backed up safety profile, traditional medicines integrated with modern medicines can open up a new avenue for the treatment as well as for the prevention of diseases, thus, helping in achieving the ambition of Make in India for the pharmaceutical industry.

About the Author

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

The Heart of Pharmaceutical Marketing

Marketing is one of the most important functions of the pharmaceutical industry. Commonly referred to as medico-marketing, medical function plays a crucial role in the promotion of pharmaceutical communication. Read on to know more about medical communication as the heart of pharmaceutical marketing as discussed by Dr. Anant Patil.

THE HEART OF PHARMACEUTICAL MARKETING

"Medical communication is the heart of pharmaceutical marketing because it can lead to actions by healthcare professionals impacting lives of patients."

The pharmaceutical industry is a regulated industry. Marketing is one of the very important and demanding functions in this industry. Pharmaceutical marketing is commonly known as "medico-marketing" because of the involvement of both (medical and marketing) the functions in this activity. As the first half of the term "medico-marketing" suggests, medical function plays a crucial role in pharmaceutical promotional communication.

Medico-marketing is an art of communicating scientific messages in effective way which would help the healthcare professional in his/her clinical practice for a better management of patients.

Challenges Faced

First challenge faced by the medico-marketing function today is the differentiation of messages in the light of strong competition between various companies and their brands.

The generic dominated nature of the market leaves limited scope to discuss newer advances/clinical trial data, thus, posing as a challenge to the medico-marketing function.

Next challenge is the limited time available for discussion with physician along with increased knowledge of the physician.

These challenges make the job of marketing and sales team tougher compared to other industries.

Components for Effective Medico-Marketing

The successful medico-marketing needs to be an effective blend of strategies, execution and outcome measurement.

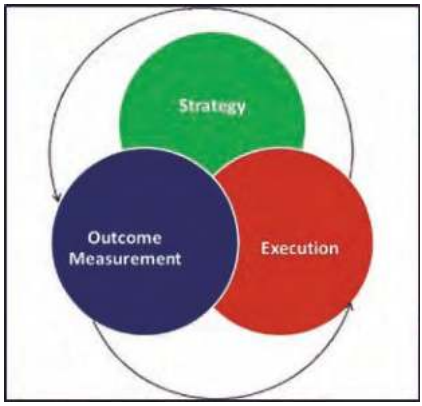

Fig. a. Effective Medico-Marketing

1. Strategy: The medico-marketing team should focus on the physicians' needs. For example, the communication should be targeted to provide solutions to the challenges that a physician faces during his practice. The principle of "Know the needs of your customer" applies equally to pharmaceutical marketing as to other industries.

2. Execution: The factors that make a medical representative standout over the others are a) communication skills and b) training. Periodic training, both in science and soft skills of medical representatives are very crucial.

3. Outcome Measurement: An increase in sales is an indirect indicator of effective medico-marketing which might be confounded by other factors (e.g. an increase in number of patients due to an epidemic). Interviewing healthcare professionals is one direct method to understand the effectiveness, recall and usefulness/relevance of communication in routine clinical practice. Subjective response is a limitation of survey. In the absence of any validated method of outcome measurement, combined analysis would be more appropriate and may yield more reliable data.

First two processes are rigorously followed by most pharmaceutical companies; however many lack focus in the last activity i.e. outcome measurement.

Guidelines for Medical Communication

The communication should be accurate, fair, balanced, updated, unbiased, accurate, and complete.[1] The communication should be supported by the evidence and importantly, it should be restricted to the approved indication by the regulatory authorities.

The information provided should be up to date; the guidelines/recommendations referred should be latest and relevant for the disease under discussion.

In addition to an individual company's promotional policy, there are different guideline documents for understanding principles of pharmaceutical marketing and promotion. The two important documents are:

1. Organization of Pharmaceutical Producers of India (OPPI) Code of Pharmaceutical Practices.
2. The Uniform Code of Pharmaceutical Marketing Practices (UCPMP) is also issued by the Department of Pharmaceuticals, Govt. of India.

'PICO' Principle for Medico Marketing

There are chances of bias in pharmaceutical promotion, especially overestimation of efficacy and underestimation of the safety, while narrating the clinical trial results

Describing results of a clinical study with 'PICO' elements might be useful to give better overview of the trial:

P: Population

I: Intervention

C: Comparison

O: Outcome

Population
Under the population, describe the characteristics of the study subjects (e.g. healthy volunteers/patients, type and stage of the disease, gender, age group – the demographic characteristics).

Intervention
Communicate the study design (randomized/non-randomized, blinded/open label, parallel/crossover, duration of study, dose of medicine). It is possible that the dose used in the study is not as per approved label of your product. In such a case, specify it.

Comparison
Write whether the study was placebo controlled or only active controlled.

Outcome
Efficacy as well as safety outcomes should be carefully noted. While describing the efficacy outcomes, it is important to communicate the outcome of primary efficacy parameters rather than discussing favorable results from secondary efficacy or other parameters.

Conclusion
1. In the highly regulated pharmaceutical industry medico-marketing function plays an important role in dissiminating scientific information to healthcare professionals,

2. The relevant communication should be unbiased and based on latest supporting proven evidence

3. The principle "PICO" is very useful while describing clinical trial results in the promotional materials.

About the Author
Dr. Anant Patil is a MBBS, MD (Pharmacology), MBA and has close to 10 years of experience in Pharmaceutical industry, He has worked as a consultant for medical communication, training and strategy. Dr. Patil has also worked for various prestigious pharmaceutical organizations. He has authored and has close to 20 papers in various journals and conferences to his credit. He is the medical consultant to Interlink.

Measuring African Pharmaceutical Potential

Africa is a vast and highly diverse continent with great potential for growth in the coming years. Even with the African market being in the nascent stage, its importance is significant. Read on to know about measuring the potential of the African pharmaceutical industry as discussed by Ms. Shreya Pathare.

MEASURING AFRICAN PHARMACEUTICAL POTENTIAL

Africa is a vast and highly diverse continent with great potential for growth in the coming years. Even though the African pharmaceutical market is at a nascent stage, its importance is significant and is not far behind the Southeast Asian market. Africa's pharmaceutical market has huge prospects for boosting economic growth and creating jobs. Given the current sustained and rapid economic growth, the African pharmaceutical industry, like that of other emerging markets, is expected to grow tremendously in the coming years.

Overview of the Pharmaceutical Market in Africa

The pharmaceutical market in Africa showed tremendous growth from USD 4.7 billion in 2003 to USD20.8 billion in 2013. The African pharmaceutical market is growing fast with a CAGR of 10.6%, which is second to the Asia Pacific region (12.5%) but higher than the Latin American region (10.5%). Looking at the current growth rate it can be estimated that the African pharmaceutical market would be valued at USD 45-60 billion by 2020.

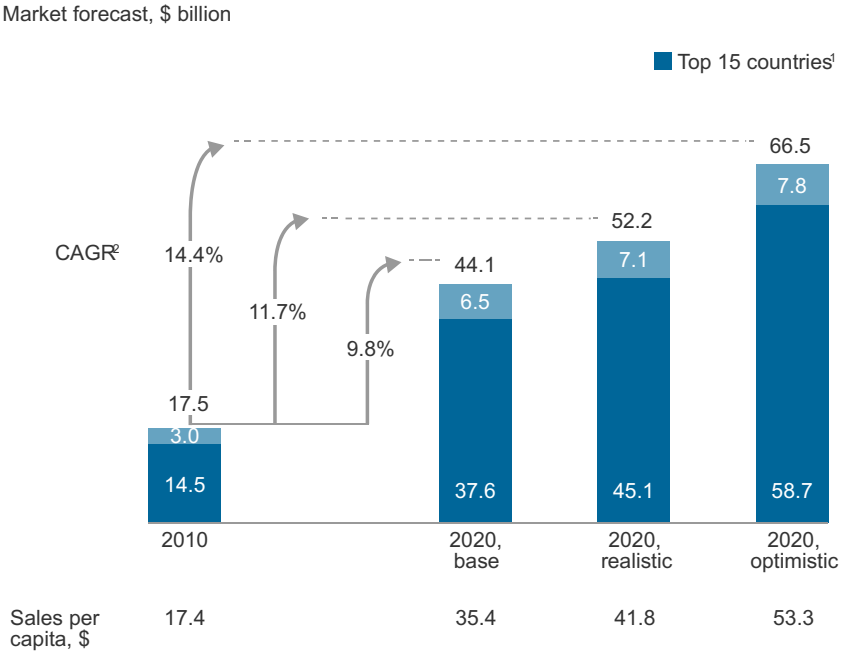

Fig. a

Source: African Development Bank; BMI Research; International Monetary Fund; World Bank; World Health Organization

The pharmaceutical imports in Africa were valued at USD 481miliion in 2013 and are expected to gain 10.4% to reach USD 789million by 2018, widening the country's pharmaceutical trade deficit from USD 475million in 2013 to USD 778million in 2018.

With the Asian and Latin American markets beginning to attain maturity, Africa shows a lot of potential and promise for the pharmaceutical sector along with remaining a niche marketfor the next decade.

South Africa, Egypt, Algeria, Morocco and Nigeria contribute approximately 70% to the value of the pharmaceutical market in Africa with the rest of the continent contributing to 30% of the total value. Two of the biggest high-growth cities for sale of drugs in Africa are Lagos and Cairo.

Irrespective of this, local production remains weak and limited with local manufacturers producing only 25%-30% of pharmaceutical products that are on the African pharmaceutical market.

The African pharmaceutical market is majorly constituted by small, privately owned companies, public sector manufacturers along with a few large manufacturers with the likes of Sanofi and Aspen.

Sanofi, which has its foothold in the African pharmaceutical market since 1953, has Algiers on its priority list. Already with two factories in Algeria, Sanofi is investing USD 70-million in a new pharmaceutical manufacturing plant on the outskirts of the capital.

The African pharmaceutical market also reflects an uneven structure with a broad approach towards prescription and over-the-counter drugs. As a result, GlaxoSmithKline is betting on expanding over-the-counter sales to 80%, so that it can hold its presence in the Nigerian products unit, selling painkiller Panadol and Sensodyne.

It is not only the country's economic growth that is favorable but also the shifting nature of the disease burden is attracting big pharmaceutical companies for treating chronic diseases rather than just fighting infections.

Drivers Facilitating Growth

Growing Middle Class Population

The world has its 14% population living in the African continent. With a growing middle class population, the annual disposable income is expected to reach USD 1 trillion by 2023.

Rising Economic Standards

The rising economic standards have also improved the standards of living of the population in Africa. The adoption of a more Westernized lifestyle has led to significant shifts in the disease patterns in the African continent.

Disease Burden

Africa bears the greatest disease burden in the world. 75% of the world's HIV/AIDS cases, 90% of deaths by malaria and majority of tuberculosis cases are all evident in the African continent. Two-thirds of Africa's disease burden is constituted by infectious diseases, maternal and perinatal conditions and nutritional deficiencies.

Non-communicable diseases like cardiovascular diseases, lung disorders, diabetes and cancer are expected to account for 46% of all deaths in the African continent by 2030.

The rising non-communicable diseases with the communicable ones along with the emerging infections need new medical services and medical treatments in Africa.

Healthcare Infrastructure

African cities are slowly experiencing better logistics infrastructures and healthcare capabilities leading to more purchasing power and better adoption of modern medicines.

Statistics indicate that Africa has added 70,000 new hospital beds, 16,000 doctors and 60,000 doctors between 2005 and 2013. Initiatives like Mozambique's switch to specialist nurse anesthetists and South Africa's initiative to use nurses for antiretroviral drug therapy has made healthcare provision more efficient, thereby increasing the capacity of the pharmaceutical sector in Africa.

Alliances

Africa's pharmaceutical market is witnessing consolidation of pharmacy chains, horizontal and vertical integration and expansion of local manufacturing. This along with a range of mergers and acquisitions, joint ventures, alliances, partnerships and private-equity deals are further driving the growth of the African pharmaceutical market.

Government Efforts

The African Government's efforts to improve access to healthcare aid in driving the pharmaceutical growth. One example of this is Nigeria's aim to implement National Health Insurance Scheme to provide universal healthcare to its citizens. There have also been numerous efforts by NAFDAC, the main regulatory body in Nigeria to standardize the pharmaceutical industry. The African pharmaceutical industry has also received assistance from WHO, Prequalification team (PQT) to demonstrate compliance with Good Manufacturing Practice (GMP).

Major Hurdles

The biggest hurdles of the African pharmaceutical market are lack of efficient healthcare infrastructure and unaffordability of medicine.

Reimbursement and public funding also emerge as an important constraint for growth of the pharmaceutical market in Africa along with supply chain issues.

Africa faces the challenge of inadequate number of pharmacies and private clinics leading to a weak distribution system. This weak distribution system has thus, led to the challenge of counterfeit drugs and illegitimate drug trading.

Western multinationals trying to tap the African pharmaceutical market face numerous hurdles as Africa possesses weak regulatory policies. The drug registration process in the African continent is time consuming and is susceptible to corruption. The public sector faces a hurdle by the absence of a suitable pricing structure. The private sector in turn is challenged by high out-of-pocket spending.

The patients have a poor knowledge of diagnostic procedures and tend to be skeptical about modern medicines. Also, there is a lack of trained doctors and nurses in Africa.

Even with the greatest disease burden in the world, Africa in most cases depends on externally developed and procured drugs, vaccines, medical devices and diagnostics to support the health of its population. As a result, there is heavy reliance on foreign aid with high registration fees for import of drugs.

Western companies also have to deal with cut-price competition from drugs imported from India and China, the volume of which has more than doubled in recent years.

Key Steps

The pharmaceutical companies need to build a close collaboration with the African Government in order to establish the infrastructure needed to sell or apply pharmaceutical products.

The market approaches employed in mature markets do not apply to the African market and thus, require customized approaches with flexible solutions. Due to highly diverse markets across the African continent, building close partnerships with local NGOs, packing companies, retailers and distributors, would be the most common strategy for the years to come. There is a huge need to localize certain functions like R&D, manufacturing, market access and sales and marketing to reduce the dependence on foreign imports.

Talent development is the real key. The pharmaceutical companies need to look at hiring more medical representatives, building teams' technical skills, and selecting and developing strong local managers to lead them. The sales teams need to be flexible in order to be responsive to the need of the market.

Price reductions would help also to address issues of affordability and social responsibility.

Conclusion

With the growth of major pharmaceutical markets in the world slowing down and stagnating, Africa is one continent where high growth is still achievable. In order to do so, it is important to know the nuances of the market in great detail along with identifying levers and movers for gaining a competitive advantage. While the stakes are high on both emerging markets and Africa, the next few years will be vital for these drug companies as the pharmaceutical industry steps into a new defining phase.

About the Author

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

Controversial Look of Anti-Oxidants

Several studies on anti-oxidants have revealed that these agents not only fail to protect against diseases, but also some of them accelerate the development of cancer or cardiovascular diseases. Read on to know about the controversy surrounding anti-oxidants as discussed by Dr. Dilip Ghosh.

CONTROVERSIAL LOOK OF ANTI-OXIDANTS

An antioxidant is a synthetic or natural compound capable of slowing or preventing the oxidation of other molecules. Most commercial food antioxidants work by scavenging free radicals or chelating metals. It is well known that oxidation damages various biological substances and subsequently causes many diseases such as cancer, liver disease, Alzheimer's disease, aging, arthritis, inflammation, diabetes, Parkinson's disease, atherosclerosis and AIDS. As a result, many diseases have been treated with antioxidants to prevent oxidative damage. At the same time, several disease conditions also altered the level of oxidative damage in our body.

Several past and recent human intervention trials have given mostly negative results and some meta-analysis and other studies suggesting that these agents not only fail to protect against disease, but also that some of them accelerate the development of cancer or cardiovascular diseases. This obviously raised concerns about the century-long held belief in antioxidant's health benefits to humans.

The Antioxidant Controversy

Antioxidant research and outcomes have generated more controversial opinions than any other scientific subject. The topic being discussed is not only in scientific literature, but also in the lay press. A Google search combining the words “antioxidant” and “health” gives over 82 million entries. These controversies inevitably hamper research in the field, confusing both scientists and consumers and generating a wide range of misconceptions. Bast & Haenen (TIPS, 2013) nicely documented these misconceptions.

1. Antioxidants cure any disease.
2. Antioxidants increase mortality.
3. The more the better.
4. At high doses, antioxidants become pro-oxidant.
5. Any antioxidant will do.
6. Theoretically, antioxidants cannot behave as such.
7. Antioxidant status measures health.
8. Once used, antioxidants are inactive.
9. Natural antioxidants are superior.
10. Antioxidant drugs do not work.

Consumer Perception

Product differentiation is the center piece of a successful campaign to win over the better-educated, cost-conscious consumers in today's crowded market. The Baby Boomer category is one of the most affluent and well educated, and they are willing to spend the dollars on health maintenance and improvement through nutrient enhanced foods.

At the same time the younger people, those trying to sustain a healthy, energetic lifestyle – are also a target for this antioxidant campaign. According to some estimates, around half of the US adults take antioxidant pills daily.

To attract consumers to the use of the word "antioxidant" on the label of food products is increasing, and numerous assay methods have been developed to measure this antioxidant potentiality. Among them, food manufacturers are beginning to use values from assays like ORAC (oxygen radical absorbance capacity) and DPPH (2, 2'-diphenyl-l-picrylhydrazyl) to emphasize the antioxidant profile of their products. However, according to new research from the Department of Food Science at the University of Massachusetts, basing antioxidant activity claims on the results of basic antioxidant assays such as ORAC and DPPH could be misleading. The results from the free radical scavenging assays are not consistent, sometimes even confusing.

Accordingly, these data from these assays should not be used to imply that compounds with high free radical scavenging capacities are good antioxidants in food systems. According to their findings, the ORAC results showed that, of the tested compounds, ferulic acid performed best, followed by coumaric acid, propyl gallate, gallic acid, and vitamin C (ascorbic acid). On the other hand, the DPPH for non-polar compounds showed that rosmarinic acid came out on top, with higher values than butylatedhydroxytoluene, tert-butylhydroquinone, and vitamin E.

Behind the Theory

The antioxidant hypothesis implies that all changes associated with reactive species activity are undesirable and the action of antioxidants beneficial. This is particularly significant as some dietary compounds have beneficial activities, which are not direct antioxidant effects (e.g. glucosinolates) while others (e.g. vitamins C and E, and the carotenoids), previously recognized only for their classical antioxidant characteristics, are also being shown to induce other biological responses.

In recent years, several experiments demonstrated that all reactive species act as signaling molecules in cell function, proliferation and differentiation, and cell death, and that has altered this over simplistic "antioxidant theory." Such modes of action result in longer lasting cellular changes, by modifying gene expression. Certain compounds have been shown to enhance endogenous antioxidant potential by upregulating the expression of cytoprotective, detoxifying, and antioxidant genes.

Unfortunately the majority of data available to support this theory has been obtained from cell culture and animal experiments and the relevance of these data, obtained under non-physiological conditions, needs to be reassessed. Ultimately, antioxidants cannot be pinned to one mechanism of action, i.e. scavenging of radicals, but will be based on inflammation, immunity and oxidative stress. Future health claims could focus more on this "trio," which better reflects biological activity and is more relevant to human disease prevention.

Outside or Inside?

There is a big question of whether antioxidants should be present inside the cell for full efficacy?

The general consensus is that the internalization of antioxidants in cells is of importance, but in particular many phytochemicals are only partially bioavailable,

so they might not reach relevant concentrations within a cell. The most rational scientific opinion is, although each antioxidant compound might only be present at a low concentration, effective potentiation can be achieved by additive and synergistic interactions of the many phytochemicals present, such as in foods or multi-component botanical preparations. Several studies showed that internalization is not a strict prerequisite for the activity of an antioxidant compound, as the gastrointestinal tract bioactivity has demonstrated at high concentrations.

Going Natural

A significant number of studies have shown that fruits and vegetables promote health, while antioxidant supplements do not.

Recent evidence for health benefits strongly support the food synergy pattern for individual foods or food constituents. Several reviews of dietary supplementation suggest that although supplements may be beneficial in states of insufficiency, the safe middle ground for consumption likely is food.

Natural Anti-Oxidants & Their Specific Activity	
Compound	**Mechanism of Action**
Vitamin E	Prevention of ROS overload, enhancement of prostacyclin release
Vitamin C	Protection against lipid peroxidative damage
Goji Berries	Increase of endogenous anti-oxidants & inhibition of lipid peroxidation
Thymus Extract	Free radical scavenging activity & anti-microbial activity
Rosemary	Increase of NO, inhibition/ suppression of inflammatory markers
Green Tea	Anti-inflammatory activity
Ginseng	Inhibition of lipid peroxidation, reduction of platelet aggregation, serum cholesterol & triglycerides
Garlic	Increase of NO & endogenous anti-oxidants

Fig. a

Source: Adapted & Modified from Bielli et al. 2015, Life Sciences, 143

The food synergy concept supports the idea of a variety in diet and of selecting nutrient-rich foods. Also food must survive the gastrointestinal digestionand be bioavailable in a biologicallyactive form to deliverhealth benefits. The American Heart Association (AHA) does not approve of taking antioxidant vitamin supplements to improve your health. They believe that natural antioxidant foods are better. The AHA argues that there is no evidence that antioxidant supplements provide cardiovascular protection.

On the other hand, intense marketing propagandas argue that antioxidant supplements are beneficial for your health. A supplement can help the consumer to achieve a proper antioxidant intake even if they don't get it with food. Ultimately it

makes sense to include as much antioxidant food into the diet as possible. This is especially the case since most fruits are not only a rich antioxidant source, but they are also high in fiber and low in fat.

Good-Bad-Ugly?

The over representation of antioxidants in food might lead to reductive stress and an associated development of adverse effects.

Generally beneficial and health-promoting effects associated with particular plant derived antioxidants are of relevance to lower oxidative stress conditions, while the development of allergies, asthma, and obesity has been discussed in relation to antioxidant overload. Several recent reports have demonstrated the potential link between cancer development and antioxidant and vitamin supplementation (Zuo et al. 2015. Acta Physiol. 214).

Regulation Guidance

In June 2008, the US Food and Drug Administration (FDA) published guidance to help small companies comply with the labeling of antioxidant products and high potency products. The guidance confirms that describing the level of antioxidant nutrients present in a food is a nutrient content claim, and may be used on food labels in conjunction with food regulations (21 CFR 101.54(g)).

However, antioxidant nutrient content claims can only be made if the nutrients have an established Reference Daily Intakes (RDI), as well as scientifically recognized antioxidant activity. In order to use a "high in antioxidants" claim, the food would have to contain 20 percent or more of the Daily Reference Value (DRV) or RDI per serving.

For a "good source" claim, the food would have to contain between 10-19 percent of the DRV or RDI per serving. In other countries such as Australia, Canada and the European Union region, there is no antioxidant-specific regulation. Most of the claims in relation to antioxidant are centered on nutrient content or nutrient profiling.

A Marketing Challenge

Today's consumers are not satisfied with a generic antioxidant benefit unless their activity offers proven health benefits through clinical trials. A good example is Danone removing Essensis, an "inside/ out" beauty product that contained borage oil, vitamin E and green tea-derived antioxidants, from the French market.

The USDA has removed its USDA Oxygen Radical Absorbance Capacity (ORAC) Database from its NDL website, citing "mounting evidence that the values indicating antioxidant capacity have no relevance to the effects of specific bioactive compounds," and the claim ORAC values are "routinely misused" by food and dietary supplement manufacturingcompanies to promote their products and by consumers to guide their food and dietary supplement choices. In the past, ORAC value has beenthe most frequently cited scientific backing for an antioxidant

product. In reality, ORAC is only one piece of the whole antioxidant puzzle and there are new, biologically relevant assays that can justify antioxidant measurement from scientific point of view.

Way Forward Message

Experts suggest (Murphy, 2014, FreeRadBio) "to stop thinking of antioxidant therapy as a branch of nutrition and instead view it as a drug discovery and development program."

It is scientifically realistic to look beyond the traditional "antioxidant box" and possible "to design a molecule with the appropriate chemistry to selectively decrease the concentration of a defined damaging reactive species at a specific stage of the pathology within the appropriate organ/cell/ subcellular location, sufficiently to bring about a clinically significant improvement."

About the Author

Dr. Dilip Ghosh, PhD, FACN, is the Regulatory & Projects co-ordinator of Soho Flordis International, Australia. He is also professionally involved with the University of Western Sydney, Australia & is an Honorary Ambassador with the Global Harmonization Initiative (GHI).

INTERLINK BUSINESS +
STRATEGY CONSULTING PRACTICE

INTERLINK PEOPLE +
PEOPLE PERFORMANCE PRACTICE

INTERLINK KNOWLEDGE +
RESEARCH & INSIGHTS PRACTICE

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

Functional Practices

Business strategy plans development & growth practice
Marketing strategy & execution practice
Categories, therapies & customer insights practice
Brand management practice
Marketing practice (new product development)
Sales practice
Profit & productivity improvement practice
Business initiative practice
Capability improvement practice
Turn key projects
Business valuation practice

Industry Practice

Pharmaceuticals & Medical Products
Functional foods / Fortified Foods, Medical Foods & Nutraceuticals
Fine Chemical, Bulk drugs, APIs & ANIs
Prescription to OT_X to OTC
Personal Products
Animal Health Hospitals-Day Care centres
Diagnostics
Lifesciences
Consumers & Consumer deliverables
Financial services

To be on our mailing list, send us an email at info@interlinkconsultancy.com or speak to us on 022 2666 6611 / 44.

You can also connect with us through our website www.interlinkconsultancy.com and join us on Interlink LinkedIn forum.

INTERLINK PROJECTS +
TURN KEY PROJECTS

IPA(MSB)-Interlink
Skills development academy

Moving Beyond Academics Towards Employability

Get Certified As a Brand Ambassador

Designed Exclusively for Pharma Industry & Pharmacy Students

IPA(MSB)-Interlink Skills development academy

INFLUENCE • ACHIEVE • CONQUER

CERTIFIED COURSE

JOIN US TO ENHANCE YOUR SELLING SKILLS

CONTACT US:

Indian Pharmaceutical Association-Maharashtra State Branch
Bombay College of Pharmacy Campus Kalina, Santacruz (E), Mumbai - 400 098. **Tel:** +91-22-26664568 / 26671032
Email: iisakalinamumbai@gmail.com

INTERLINK MARKETING CONSULTANCY PVT. LTD.
3A, Central Plaza, 166, C.S.T. Road, Kalina, Santacruz (E), Mumbai- 400 098. Tel: 022-2666 6611 / 2666 6644
info@interlinkconsultancy.com I www.interlinkconsultancy.com