



Pharmaceutical Industry

Opportunities Abound!

Global life sciences and healthcare domain presents significant growth opportunities and also enumerable challenges. To take advantage of this situation and sustain growth, Indian pharma companies need to engineer & deploy right strategies, manage risks and build 21st century healthcare solutions, say Stephen Watt and Harsha Kapoor of Pharma Alliance International.

Never has there been a more exciting time to be in the global pharma and healthcare market. The need for wellbeing is greater than ever; more people living longer, having access to more treatment options, new science and technology, global supply chains, and emergence of new models of deployment and efficiencies. Though there also exist considerable risks and uncertainties in many areas which include slowing global growth, national healthcare budget constraints, a changing regulatory environment, and growing competition.

Indian companies are emerging as key players in the global pharma space and are becoming a major supplier to global markets. Whilst there are inevitable challenges around sustaining growth, the most important thing as “players in the game” is that Indian companies must take advantage of this situation and build 21st century healthcare solutions. Besides, they also need to engineer and deploy right strategies, manage risks, enhance capabilities, focus on customers and improving patient outcomes and deliver.

Change, Uncertainty & Opportunity!

Opportunities in global life sciences and healthcare domain are being driven from a strengthening science base and increasing knowledge about disease mechanisms, driven in part by genomics and new technologies as well as the integration of data and information. For example, telemedicine and the combination of patient, clinical & lifestyle data

will become a powerful mechanism for the delivery of care, and improving patient outcomes. Whilst controversial in terms of the exchange of sensitive medical data, there is no doubt that using more focussed data in both diagnostics and the application of care will open up new opportunities. Integrated still further into research and development it has the potential to drive stratified and tailored healthcare provisioning and radically new products and treatments. Reviewing major initiatives, such as Europe’s Horizon 2020 program for health, has a focus on:

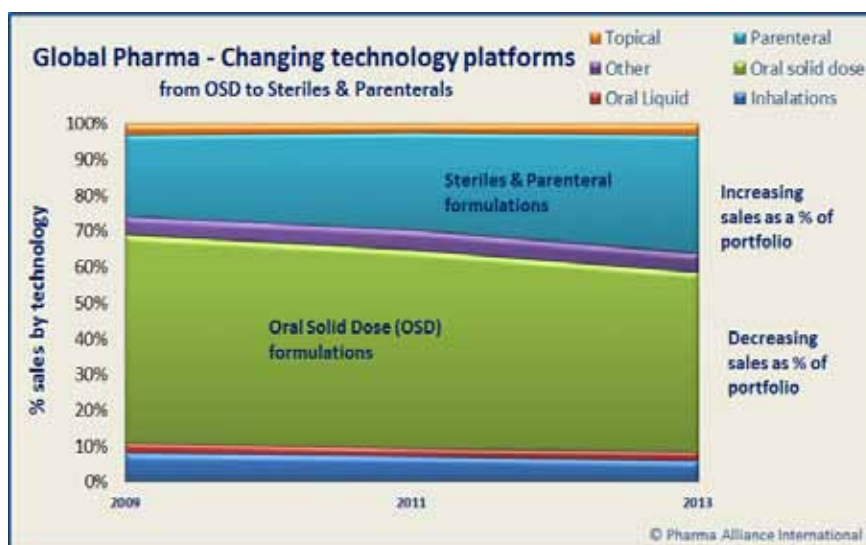
- Personalising health and care
- Understanding health, ageing and disease
- Effective health promotion, disease prevention, preparedness and screening
- Innovative treatments and technologies
- Advancing active and healthy ageing

There is an escalating global demand for medicines and services. Population is growing in all major markets. Demographically

people are living longer and have more care needs. In addition, there are an increasing number of treatments & care options. This dynamics together with ongoing trade liberalisation and global supply chains will open up further opportunities.

However, there are significant challenges as well. Given the promised breakthroughs that were expected from genomics and enhanced candidate screening processes, we continue to see a relatively poor record of scientific productivity and new products introduction. In addition, regulatory authorities continue to review and tighten regulations & standards for products in key markets. The general global economic crises is still washing through into national healthcare budgets and is creating difficult trading conditions.

Healthcare provisions around the world continue to rise and governments are seeking to restructure service and reduce overall costs. There is an increased focus on pharma economics, and the societal impact of poor health and factors that contribute to it. At the



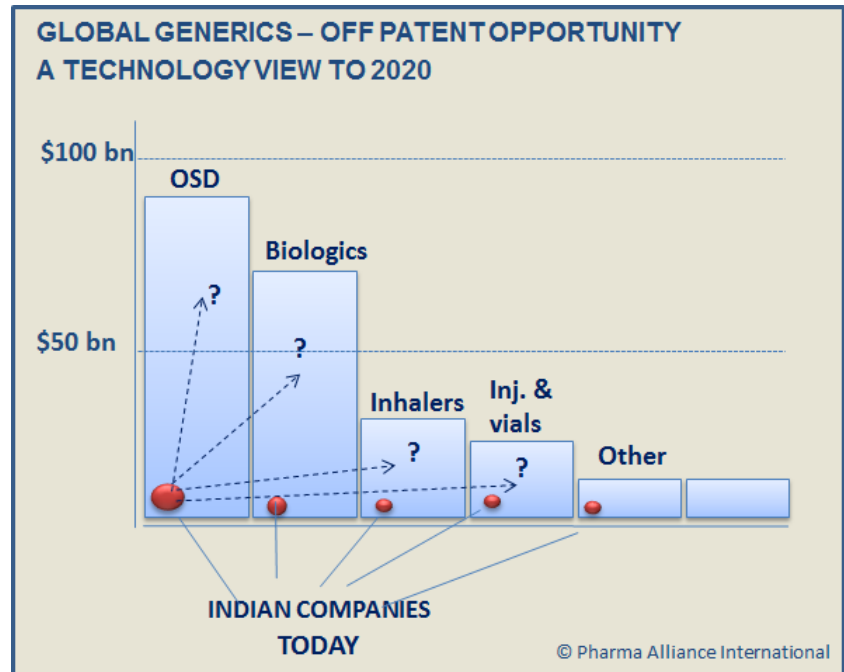
same time, as far as the suppliers of products and services are concerned, there is increasing competition for medicines and services.

Large global pharma companies have responded to these opportunities by focussing on biologics and seeking growth through more sophisticated and effective science driven solutions and technologies. From a manufacturing and supply perspective this has an impact on the technology - the platforms used for delivering medicines.

The changing technology base inside large global pharma is highlighted above. The top 25 companies' combined portfolios now have over 33% of sales generated from parenteral technologies (sterile forms such as pre filled syringes, vials and ampoules). These companies account for over 50% of sales in the \$1,000bn global market of 2013. More complex delivery and formulated products (more effective release and control of the active substance) are also taking an increasing share in the portfolio.

This trend in biologics driven discovery will continue, changing the shape of the companies', and as we move forward to 2020, the industries portfolio of technologies will further change and evolve. These large global companies continue to spend from 10 to 20 per cent of their overall sales in R&D. In the life sciences industry overall, the biopharmaceutical sector accounts for 85 percent of all R&D expenditures.

Several companies in the global market space have achieved considerable growth by focussing on emerging markets, over the counter products (OTC), contract manufacturing, and generics products



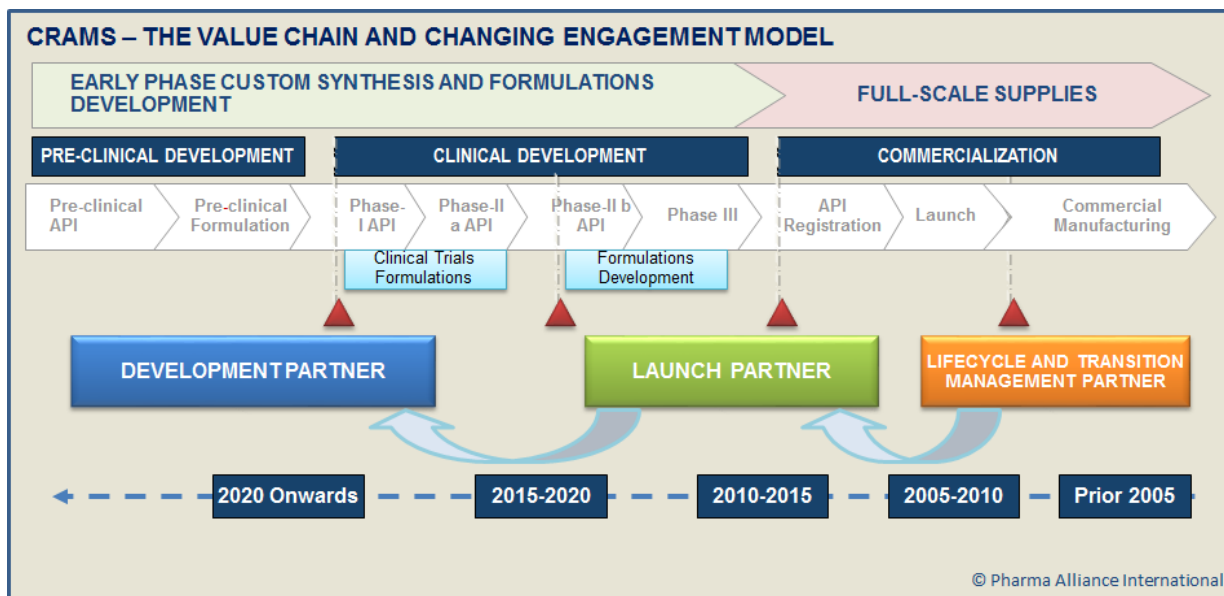
created by going after products in the enormous “off-patent” market. A market created by loss of exclusivity in the tail end products of the originator companies. Global generics has had a long history of steady market growth, however formulation and delivery device technology is becoming more complex. This will bring challenges in both regulatory and supply. Over the next few years between \$20bn and \$60 bn will go “off patent”, each year.

Global generics market is a very complex market, characterised with increasing commoditization of product, ongoing reforms in regulated and unregulated markets, increasing price pressures and tender approach taken by big buyers. While companies can go after more complex portfolios and technologies (products and processes), there is a long gestation period and inherent risks in such approach. At the same time, the future “Off Patent” products are more complex and include drug/device combination products, sterile injectable and biologics.

While North America and Europe are large markets, they, however, are highly competitive and new players are entering these markets on an ongoing basis, including originators businesses like Abbott, Sanofi, Novartis, and so on. Moreover, these markets have very high and stringent quality and regulatory compliance requirements.

Companies can explore growth opportunities in differentiated generics - Biologics, Inhalers and Nasal preparations, Parenteral, Transdermal, etc, as well as the ‘over the counter’ (OTC) market. Each technology area brings different revenue potential, and presents different supply challenges, regulatory needs, process & asset requirements, and requires a focussed commercialization and go-to market strategy.

While leveraging India’s cost advantage, it is prudent for players to excel in product development, supply and technical operations. This will help them in handling greater complexity, ensuring quality and compliance and de-



delivering products through, extended, and higher performing supply chains.

Capitalizing on CRAMS

CRAMS, the contract research and manufacturing market will continue to grow as large global businesses seek greater cost competitiveness and choose to outsource more and higher end research activities. Restraints to growth include getting the right capabilities and expertise in place, addressing intellectual property (IP) protection concerns, as well as skill development and the retention of key personnel.

Indian companies have a proven record in terms of cost competitiveness, product quality, GMP (Good Manufacturing Practices) Compliance and international standards. India is one of the leading countries in DMF (Drug Master File) filings within the US, and has over 120 FDA approved sites. A new model and partnership arrangement is emerging in the global CRAMS space. In the past, it's been a focus on commercial-

ization (a life cycle and service partner), this has grown into a launch partner relationship, including clinical development activities. In the future, 'development partners' will be sought to include pre-clinical work. Indian pharma companies have to plan and invest effectively to move up the value chain, as global majors will require more "one stop shop" aspects and a partner relationship that shares the risk.

India is well positioned as a supplier of contract research and manufacturing services (CRAMS), notwithstanding the challenges above, and can do more in the burgeoning global generics market.

The Way Forward

Key strategic questions that Indian companies needs to address, as they plan to further grow in global pharmaceuticals market, can be categorised into What Products?, What Market?, How and Who with?

What Products?

Bio similar products are a clear

target given the scale of opportunities, but regulatory concerns will bring challenges and risk. Being more proactive with regulatory authorities, especially around product characterisation is to be encouraged.

The respiratory market is opportune, but risks again have to be managed, such as a history of in market product approvals problems and the additional supply chain capabilities that are needed to handle more complex devices, their assembly & sourcing of componentry and materials.

The parenteral market with its wide range of sterile forms from vials, to ampoules to pre filled syringes brings technical challenges, not just in product, process and supply conformance but in high grade facilities and compliance standards.

The oral solid dose (OSD) technology is clearly the most robust technology within the industry and is still the preferred form for ease of use and drug delivery.

Flexibility and a focus in OSD sub technology manufacturing & supply will bring advantages.

Companies can explore opportunities in a more stable OTC market, but that will require brand building and marketing assets to ensure traction and growth, as well as cost and quality leadership.

What Markets?

The US and European markets still remain the most significant business opportunities, however, partnerships and extended supply chains adds complexity, and may require new business models.

There has been much focus on emerging market opportunities of late and while they offer returns each has different dynamics & market complexities. For example price erosion and often large volumes, places additional pressure on companies supply costs & overall productivity of assets.

How and Who with?

Successful businesses have to secure capability, capacity, reach and strengthen portfolios. One route will be to partner and create venture relationships. The JV process, acquisition strategy and deal making processes will be fundamental in deciding what partnerships should be forged, why, with whom, as well as what kind of business models are best for all concerned. Price and valuation of target companies will remain a challenge. This will put a greater emphasis on well-executed post acquisition integration (PAI) strategies to leverage full potential in the acquisition or merger.

A key question for senior manag-

ers is the positioning of the “war chest” needed for growth; detailing the financing and investment needs to drive new ventures, processes, practices, buildings, capabilities, skills and people.

Indian pharma companies have to continually seek innovative solutions to strengthen the business, drive productivity and improve returns. They have to implement a strategic review and benchmarking process for strategic direction setting and driving top-tier business performance. All of this creates a complex business space where sound strategies and decision making is required to ensure success and manage risk. In addition, operational excellence in all parts of the company will be fundamental.

There might be an increasing trend for companies to create more supply centres as close to the market as possible, taking the opportunity to automate and engineer out direct labour costs. This again brings new challenges especially around the supply of regulated modular type solutions for increasingly diversified supply chains (including packaging operations). Equipment manufacturers (OEMs) have a role in supporting pharma companies meet quality goals, drive productivity & improve returns through appropriate design, installation and maintenance of equipment.

There will be a trend to integrate data and provide new platforms, such as telemedicine, as well the continued growth in the use of informatics, genomics and integration of personalised data. India

is well positioned to build on its informatics and solution build experience, capabilities and reach. Improving health outcome will be the goals, but productivity in supply and deployment will also play a major part to balance the growing cost of healthcare provision. India should be clear on its global role as some of the major markets move to stratified, personalised and tailored healthcare systems.

Internally, the Indian market will continue to mature, with a growing group of over 350 million Indians wanting more from healthcare and health provision. Private and public models will be employed to meet this need. The Indian ambition should include the continued leverage of higher education and the pursuit of next generation products and services around biologics & gene therapies. Although providing the technology clusters and the deep capabilities needed to rival other clusters around the world will continue to be a challenge.

With a stable government at centre, India has taken several initiatives to provide a conducive business environment. With an impetus on developing industrial corridors, government is opening Hi-value sectors for global participation. The IP regime is being strengthened and process of approvals and clearances is being made simpler to encourage entry of foreign players. However, companies need to focus on the right opportunities, and have a robust roadmap and risk management practices to partake of the opportunity in India.

Exciting times indeed. ■