BioSpectrum the business of Bio & Health Sciences

GameChangers of the decade

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ost graduate in pharmacy from Andhra University, Visakhapatnam and a registered pharmacist in the n the US returned to India in 1989 and has been promoting Suven since then, in the capacity of the viding the direction and leadership in developing innovative business models like CRAMS (Contract ufacturing Services), DDDSS (Drug Discovery & Development Support Services) which led to rch Partnership (CRP) in drug discovery with global pharma giants such as Suven's CRP with Eli Lilly

Mr Venkat Jasti, chairman & CEO, Suven Life Sciences

S ngers in the pharma industry over the next decade may be:

Biology: A remarkable leap forward in how well we understand some biological mechanisms, which will lead to new innovations. Biologics: The field of biologics will be exciting because we can apply new science and technology to the development of important new medicines.

Personalized Medicine: Personalized medicine will be another area which will unearth a new era of healthcare through improved diagnosis, earlier interventions, more efficient drug development and better medical outcomes.

Healthcare reforms, FDA policies and guidelines will have a major impact on drug discovery and development.

Biosimilars and NDDS will lead to product life cycle management.

Ever greening of patents

will be fiercely opposed by developing countries.

Blockbuster scenario will be a thing of the past and generics may not the mainstay of the generic companies alone.

Evolution of new business models: The industry needs a new approach and new business models will evolve.

Finally, the emergence of a major Indian or Chinese drug company with innovation capabilities will be the real gamechanger.

Biology

The pharmaceutical industry is moving from a symptomatic relief focus towards a more pathology-based approach where a better understanding of the pathophysiology should help deliver drugs whose targets are directly involved in the causative processes underlying the disease. The impact of biology across the whole process of drug discovery and development, including (i) the identification and validation of new drug targets, (ii) the development of molecular screens to find new candidate drugs, and (iii) the generation of safety data and competences leading to enhanced clinical efficacy and even more vital role in the generation of future therapies.

Biologics

Biologics may represent about one in every three newly commercialized drugs and will be the most exciting areas of therapeutic medicine in the future. This biology-based drug discovery and development will be a natural complement to the chemistry-based small molecule, transforming pharmaceutical industry into a biopharmaceutical industry.

Personalized medicine

Personalized healthcare is a broad term for interventions that are targeted to individuals based on their risk in order to provide a more coherent and focused approach to healthcare. Personalized healthcare includes preventive, diagnostic, and therapeutic interventions, with risk defined through genetics as well as clinical and family histories. Personalized medicine goal includes greater effectiveness and efficiency of healthcare delivery as well as improved health outcomes and quality of life.

Healthcare reforms

With healthcare reforms happening all over the globe, government's role will expand as a customer for medicines, medical devices and services. But the reform laws also have a huge impact on the life sciences industry's other highly influential customers, such as health plans, providers and state governments which will have tremendous cost pressure and intense scrutiny from the governmental agencies. Industry should be prepared to defend prices and invest in product effectiveness.

Biosimilars

Biosimilars or follow-on biologics are terms used to describe officially-approved subsequent versions of innovator biopharmaceutical products made by a different sponsor following patent and exclusivity expiry on the innovator product. The opportunity in biosimilars is not exactly â€œnewâ€?, but prior rules (and the uncertainty of how the FDA would apply those rules) largely kept this market empty. Now, though, with the Pathway for Biosimilars Act of 2009 and the Patient Protection and Affordable Care Act of 2010, there is more clarity than before and a reasonably clear mandate from the US Congress for the FDA to act more openly and decisive. A well-crafted pathway for the approval of biosimilars will lower costs through increased competition, expand access to lifesaving medicines, protect patient safety and promote further biomedical innovation.

NDDS

With more drug patent expiries over the next few years, the loss will be an estimated $140 billion by 2016 and big pharma is under intense pressure to replace these losses with new or improved drugs. Against this background, pharmaceutical companies are recognizing that drug delivery technologies are a powerful strategic marketing tool to differentiate products and extend product life cycles, thereby overcoming many marketplace challenges.

Ever greening of patents

Ever greening of patents refers to increasing the life of the patent or the patent term beyond 20 years to reap the benefits for much longer period of time. One form of ever greening occurs when the original manufacturer stockpiles patent protection by obtaining separate 20-year patents on multiple attributes of a single product. Many of the developing countries are not allowing patent extensions for minor product life cycle changes hence frivolous patent protection is weakening worldwide. All of the current life cycle management games will be short lived.

Blockbusters are out

The blockbuster business model that underpinned big pharma-success is now irreparably broken. The wave of blockbuster

drug patent expiries over the next few years presents an estimated $140 billion opportunity for generics by 2016. Big pharma cannot ignore this threat to their balance sheet, and will likely stem this loss by introducing their own branded generic products or buying into generics and generic companies. Generics will actually become irrelevant when the big pharma marketers lower prices and keep manufacturing even after patent-expiry, hence generics may not rest with generic companies alone.

New business models

Most Big Pharma companies have traditionally done everything from research and development (R&D) through to commercialization themselves as a Fully Integrated Pharmaceutical company (FIPCO) by spending record amounts and are slowly realizing to the fact that first-in-class, first-in-market is no longer enough and the blockbuster drug approach is a thing of the past. If they are to prosper, they will need to improve their R&D productivity, reduce their costs, tap the potential of the emerging economies and switch from selling medicines to managing outcomes and transform into a Fully Integrated Pharmaceutical Network (FIPNET) company like what Eli Lilly has done. Becoming a FIPNET means leveraging external competencies and network externally.

Over the next decade there is likely to emerge two sets of business models, one with focus on marketing and the other with long term commitment in creating novel drugs in other words pharmaceutical companies will eventually specialize in either drug discovery or marketing. Given the lack of therapies for many serious diseases and the mediocre efficacy of many existing drugs, the opportunities are huge and the development of effective treatments will be the only sustainable source of value for the pharmaceutical industry i.e., â€œinnovate or perishâ€?. There are risks in trying to discover new drugs, but the risks of backing away from that commitment are higher. Those who focus on marketing alone may do better in the short term but are doomed to failure eventually.

Likely future scenario

The next decade will witness the greatest upheaval in the pharmaceutical industry with many changes in drug discovery and development coupled with competitive atmosphere and changes in governmental policies. We may not see a dominant model in terms of size or organizational structure but will see an ecosystem of few large global players with deep scientific resources and many more specialized companies. Globalization of drug innovation will continue.

â€œA game changer, almost by definition, comes from a direction we think is unlikely and, for that very reason, we don't guard against or plan for. I think that direction may well be the East, according to Dr Brian D Smith is an author, academic, and advisor in competitive strategy in medical markets.

A real game changer for the industry may be the rapid rise of an Indian or Chinese pharmaceutical company with real innovative capabilities and a low-cost model based not only on lower labor costs but on a lean R&D and commercialization model and no one should be surprised to see the emergence of a major Indian or Chinese drug company to be that game changer in drug discovery and development by 2020.