PREVIEW OF PHARMACEUTICAL INDUSTRY AND REGULATORY AFFAIRS IN COMING 2-5 YEARS

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INTRODUCTION:

Pharmaceutical business has been changing sharply over past few decades. There had been significant changes in FDA regulations, market scenario, business models, the disease pattern and pharmaceutical technology. The newer business models are continuously evolving to meet new challenges. Currently the industry is more vigilant towards block buster drugs and formulations. The drug discovery is focused on chirality, polymorphism and genetic engineering. The industry is focusing on automation, productivity, economy and powerful drug molecules. The new treatment models using invasive and noninvasive medical devices are also explored. As per the author the pharmaceutical industry is now moving towards the low cost highly efficient health solutions. The changes anticipated in the industry in coming 2-5 years are as per below:

RESEARCH & DEVELOPMENT MODELS

There will be a rapid development in drug designing technology. The new pathways for drug molecules will become available on fast track. Eventually, the drug Molecules will be structured in laboratory the same way as we built-up complex metal structures by welding. New concepts such as Chirality and Polymorphism within a single molecule will evolve. The talent from other businesses will be researched and customized for Pharmaceutical Manufacturing. There will be new safe, economical, pollution free routes for the synthesis of API. The Single Pot synthesis will become common. There will be discovery of new drugs which are active in nanograms and pictograms against milligrams at the present. HPLC system for assay and impurity profiling of the drug molecules will be replaced by Electronic columns .The biotechnical solutions will be available for almost every major disease. There will be increased research on Pharmacogenomics and pharmacogenetics to limit adverse effects of highly toxic drug molecules .There will be increased research on humans and animal genetic materials to develop new biological products. The research on personalized medicines will intensify to match with the specific underlying causes .There will be more focus on diagnostic equipments rather than on discovery of new

drugs. The research on medical devices for replacing/correcting the diseased body parts will intensify. There will be more collaboration with academia and peers to outsource research intelligence

TECHNOLOGY MODELS

There will be increased use of Auto analyzers for the analysis of Starting materials, in process materials and finished products. Raw materials will be auto sampled, analyzed, weighed and issued for batch processing .There will be a substantial reduction in Production time cycle with the automation. The lesser time will be required for the production of drug products.. Job of 100 hours will be accomplished in a single hour. Currently impurity profiling is very tedious and expensive job for marketing authorization. The available technology is incapable of eliminating all the Impurities in the drug products. In future, it will be possible to attain "Zero Impurity Drugs" by super chromatographic technologies.

BUSINESS MODELS

There will be more focus on return on the built-up but unutilized intellectual capitals. The expenses incurred to built-up /acquire intellectual property will be encashed by some or other business means. There will be enhanced use of Business Portals such as B to B, B to C and B to E to reach more and more customers efficiently and economically. The intelligent Business Modules will be available for comparing prices, delivery and quality of raw materials will evolve. There will be more collaboration for establishing manufacturing base in Emerging Markets. The business in developed market will decline. However, the business in Emerging Market will increase. The low cost manufacturing locations such as India and China will become manufacturing hubs. The developed countries will utilize these countries as a base for highly profitable business with underdeveloped countries .In future, the presence of Pharmaceutical Companies on Social media will increase at rapid rate. Social media like Face Book will become a significant part (>10%) of the pharmaceutical marketing mix .The large pharmaceuticals companies will try to enhance their drug development pipelines through, mergers, acquisitions and licensing agreements. There will be a great focus on industry-academia collaboration to develop new drugs. The developed country will make more money by marketing their talents rather than the products. There will be increased competition for licensing of the biological blockbusters drugs .There will be increased production of Raw materials resulting in business through reverse auction. Pharmaco-economics will emerge as new discipline .The industry will continue to increase collaborations. Consequently the Royalty payments will also increase .The specific Accreditation system will be available for the recognization of Regulatory consultants and BPO .The litigations on patent issues will keep on increasing. The settlement will be very expensive. There will be greater restrictions on reimbursement of medical bills in developed countries .Pharmaceutical and biotech companies will continue to increase their outsourcing of clinical trials and related drug development. Outsourcing will account for more than 50% of R&D spending in coming years.

PUBLIC COCERNS

The health and disease knowledge of the patients will increase. The doctors will be unable to prescribe promotional drug products or high cost drug products when economical alternatives are available. The public will enjoy increased health protection and rebates on medicines. The Government will be forced to adopt Deficient Budget on healthcare. Patients will become more conscious and empowered in making healthcare decisions. The public will be benefited with the new drugs specially focused on the disease.

MARKETING MODELS

Social media marketing will become a significant part. The next BIG opportunity for targeted marketing to patients and physicians will be mobile apps on "smart phones" .Internet-based drug promotion (including search engine marketing) will overtake TV-based DTC. The role of traditional sales representative will become obsolete

TRAINING MODELS

The clinical Researchers will be trained on Pharmacokinetics, Pharmacodynamic and Toxicity of drug molecules using “see through technology .Training of the Trainer /Mentorship concept will get momentum

HOSPITAL MODELS

Robotic surgeons will be used for major operation .Stem cells will be used to create the new organ and repair the damaged ones. Artificial brain will be available. Replaceable organs will be available to substitute damaged body organs. Aging process will slow down. Internet clinics will rise .Presently, the Brain surgery is considered highly delicate and risky. However, in coming time it will become as simple as angiography and bypass surgery .Rapid mapping of human body for cancerous cells will be possible .Robotic Hospitals will come in existences. All medical functions such as diagnosis, treatment and surgical manipulations will be performed by the Robots. The physicians will be helpful in designing and training the medical robotic doctors. The automated devices will be available to check the status and functioning of delicate body parts such as coronary arteries. The Medical Device industry will provide replaceable organs. The instant checking of hydration, 5 HT, histamine and adrenaline levels in the body will be possible

REGULATORY AFFAIRS MODELS

There will be higher regulatory hurdles leading to greater uncertainty, fewer product approvals, increased regulatory actions and increased product withdrawals.

There will be Increased Bio studies and clinical trial demands all over the world including underdeveloped countries .The post-approval safety requirements and vigilance will increase

Falsified Medicine Detective and FDA Friend concept will be utilized to widen regulatory vigilance. There will be Enhanced Vigilance at sea ports/airports to restrict illegal entry of falsified medicines .FDA will make it compulsory to include "Donor section in "SOP, BMR, MMF, SOP to built further clarity in GMP Compliance. The Pharmaceutical manufacturing bases will become more complicated. FDA Control will be further tightened.

Labeling of drug products will become more stringent. The drug promotion will be sharply curtailed through public news channels .There will be improved information sharing on critical issues such as Pharmacovigilance (PV) and adverse drug reactions (ADR). The posting of ADR will become Mandatory on internet .There will be high demand for CROs for outsourcing Clinical Studies for introducing the new drugs and exploring new applications for the existing drug molecules. The CRO business in India will take a new turn with active collaborations with foreign CRO,s

The manufacturer of the drug products will prefer Contract manufacturing (CMO) over their own manufacturing facility. The Indian Pharmaceutical companies will reap full benefit of this trend.

The outsourcing of Regulatory Intelligence will increase. The Regulatory Filings will be solely handled by RA Consultants and IT organizations. The increasing number of Indian Consultants will be employed for drug registrations. The Pharma business will become collaborative. There will be active collaborations for R&D, Manufacturing, Marketing and Regulatory Compliance.

The Penalties on falsified medicines will be tightened. Many of the top companies in India and China will be banned for exports to Europe.

Unified Global Numerical code will be provided to all approved manufacturing units .The more drugs will be discovered for rare diseases .There will be more research on underlying causes of disease. The specialized drug molecules will be available for each causative factor. The treatments will be customized. The drugs will be targeted on narrow populations unlike vast population now.

There will be enhancement in demand for new drugs for Alzheimer's, Cancer, Cardiac and other Complex diseases for which drug development takes many years. There will be increased manufacturing of generic drugs eclipsing high cost patented drugs. However, the consumer psychology and brand loyalty will continue to have upper hand on generic production on patent expiration. There will be increased shift of thinking from disease treatment to disease prevention. Further the Pharma Industry will get merged with the fast evolving healthcare industry.

The CMS (Content Management Systems) for SOP, CTD/ANDA/NDA/SPL, CDM (Clinical Data Management), GxP, and electronic submissions will increase

The drug development will involve more integrated plan to develop new Drug Molecules. The review time by FDA will increase. There will be more research on biomarking, Pharmacogenomics and Individualized medicines.

The focus on South America, India, China and Russia as legitimate drug markets will intensify.

See through education and training system will be in place for Pharmacokinetic and Pharmacodynamic aspects of drug molecules .The Manufacturing, QC and QA functions will be automatically documents to meet FDA expectations. The Periodical Product Review such as APR will be computed automatically from Production and QC Records. The periodical Certification will be compulsory for Regulatory, Manufacturing and QC/QA to establish credibility on new Regulations. The clinical/toxicological trials will be conducted on Robotic system simulated to human body and physiology.

The regulatory Mentors and Consultants will command high value. The regulatory authorities will introduce special certification scheme for them .The stability testing will get automated. The Stability chambers will be connected with auto samplers and HPLC system for sampling, analyzing &computing stability of the drug products.

SUMMARY

The drug Industry will expand and specialize into new therapeutic areas rapidly in coming 2-5 years time.

There will be rapid improvements in discovery of new drug molecules and dosage forms. The industry will get fully automated. The drugs will become more specific and side effects will be reduced to a great extent. The vigilance by Heath Authorities will multiply and falsification will be prevented. Non research and unregulated companies will be side tracked and/or hammered down by FDA. The consumers and patients will become wise and will resist the medical profession for any negligence or malpractices. There will be more stress on keeping healthy. The heath authorities will be forced to ensure essential drugs at affordable prices to the public.

REFERENCES

www.news.pharma-mkting.com

www.biodeutschland.org

http://blogs.hbr.org/hbsfaculty/2010/04/pharmas-future-depends-on-thes.html

www.kpmg.com

www.siliconrepublic.com

www.manufacturing-executive.com

www.fiercepharma.com

www.bluefocusmarketing.com

www.cognizant.com

www.management-engineers.de

www.medreps.com

www.medicalnewstoday.com

www.pharmaphorum.com