Objekt: CHEManager Europe 10/08

Redakteur(in): Ana Wood

Datum: 01.08.2019

Rubrik: 65

Umfang: 7,500

Pfad Textdatei: G:\team\cm\offenneu\#CHEManagerEUROPE\65

Aufmacher:

A-Foto(s): Malhotra_Girish_Epcot_CMI1008.jpg

Bilder:

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Index: Wal-Mart, Sun Microsystems, Royal Society of UK, Imperial College of London, Medicine

Sans Frontiers,

Pharma Convergence

Challenges in Drug Development and Manufacturing Methods

A Changing Business – The global pharmaceutical world has been changing and its pace has accelerated in the last three years. Not only do they need to develop a new business strategy, they need to improve their manufacturing methods and technologies.

If the current scenario of “drying of the blockbuster pipeline” and generics increasing their market share holds, we could see most of the API manufacture, formulation and clinical testing moving to low cost countries. Since laws of economics prevail, this could be considered inevitable. Ethical and generic companies have to develop and implement strategies that could give them the competitive edge and allow them to move forward on their chosen path. Since ethical and generic producers are adversaries, it would be interesting to see the playing out of the respective strategies. Let the match begin!

Ethical Pharmaceuticals

Major pharmaceuticals have developed and commercialized blockbuster drugs. However, they have not retained these drugs in their portfolio after the patents expire, as they have been busy developing new drugs. Producing patent expired drugs has not been part of their strategy.

Due to high profit margins, generics have taken over the patent expired drugs and have lately made every effort to do so through litigation. With aggressive entry of generic producers from Israel, Iceland and India, the turbulence in the pharma field has dramatically increased.

With the drying of blockbuster pipelines, escalating clinical trial costs and relentless pressure of generics to capture the market, ethical drugs producers are trying to implement strategies to reduce their costs and retain their stronghold on the drug development chain. Some of the strategies being implemented are as follows:

- Outsource drug development
- Outsource active pharma ingredients (API) manufacture and formulation

- Synergize small molecules and/or biotech combinations
- Acquire small/large biotech companies
- Whatever else works i.e. collaborations

Some of these strategies might work as a short term fix to retain profits, however, the long-term impact of these strategies is going to be significant. The biggest consequence is going to be the shift, disappearance and/or reduction of the knowledge base from “Major Pharma” companies to the outsourced companies. Since the outsourced companies are in low cost countries, they have dual benefit of the above relationships. It makes them intellectually and financially stronger to become formidable generic competitors. We are beginning to see this happen.

Generic Pharmaceuticals

Generic pharmaceuticals are enjoying what I will call the best of all worlds. They are basking in an unprecedented growth. I do not believe any of the financial analysts and pundits would have predicted this in the beginning of 2005. Customers would like to have drugs at lower prices, generics are able to fulfill this need in every market and as a result the demand for generic drugs has increased. This surge has increased generic business dramatically in the recent years. They have utilized profits to grow organically and acquire sites that are being shed by API producers and formulators at significantly low costs. They have also benefited from the technology and intellectual property that comes with these acquisitions. Strategies being implemented by the Generic companies are unconventional and this is causing additional turmoil in the Pharma field.

Future and Strategies

Pharmaceutical companies have achieved handsome profit margins by inventing new drugs and by producing generics. Customers have paid for every inefficiency in the development, clinical testing, manufacturing and supply chain. Since pharma companies have been able to make respectable profits there was never a burning need to minimize the costs of each step. Everyone has been comfortable in their respective arenas. However, the drying of the blockbuster pipeline and generic companies trying to encroach on the playing field of ethical companies is changing the market dynamics.

The price consumers pay for drugs in the U.S. and some other countries are not market driven but rather driven by what the market can bear. Many consider these prices high and are getting low cost drugs every way they can e.g. Canada, Mexico, imports and/or Internet. This has led to considerable debate and discussions as healthcare costs increase. Wal-Mart and a few other companies are offering drugs at low prices. This puts pressure on the companies in the supply chain to continuously lower their costs. Therefore, companies will have to consider and implement new strategies.

If the major pharma companies are not able to develop new blockbuster or biotech drugs, they could start making generic drugs. This could lead to consolidation and formation of “Mega” companies. My definition of a “mega” merger is a combination of an ethical and generic company to be players in both markets. These mega companies will not only develop new drugs, but will also have to make every effort to retain the patent expired drugs as part of their portfolio. If this happens, every step of the supply chain, especially manufacturing technologies, would be critically evaluated and methods implemented to reduce costs. The business model of mega companies could be a combination of market and consumer driven companies trying to maximize their market share. This should reduce global healthcare costs.

The India government has announced an innovative drug discovery program combining global IT firms (Sun Microsystems), researchers (Royal Society of UK, Imperial College of London, Medicine Sans Frontiers etc.),

companies, and young minds at India's scientific laboratories to invent drugs at a fraction of the cost of a multi national company (MNC). An open platform of drug research like Linux development is an interesting and innovative concept and path. Success here would genericize and commoditize pharmaceuticals and add additional pressures on pharma companies to implement technology improvements to reduce costs. Other business models will emerge. I expect that more than 50% of the pharmaceutical market will become a commodity market in the next five years and we will see prices drop.

Manufacturing Methods

Improvement of manufacturing technologies has not been part of any business model. In the last few years, there has been a considerable amount of discussion on the need to improve the manufacturing technologies, nevertheless, progress has been very slow.

New business models for ethical and generic pharmaceutical companies will have to include improvement of their manufacturing technologies. Today, active ingredients and formulation are dictated by "quality by analysis" methodology. It is not the way of the future. Pharmaceutical companies have to move to "quality by design (QBD)." QBD is being talked about in the pharma world but it needs to be put into practice. Specialty chemicals, petrochemicals and other industries have produced products following QBD.

Technologies to achieve QBD exist, but need to be adopted. Improving manufacturing practices and QBD is not difficult. It requires discipline and dedication. Implementing QBD methods will change the landscape and it will be interesting to see what develops.

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