

**Summer Training at
Blue Berry Pharma Advisory
(April 04- May 27, 2014)**

**Gap Analysis of the Top Molecules in the Leading Therapeutic Segments
Using Pre-Identified Criteria
Market: Australia**

**By
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**Under the guidance of
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**MBA-Pharmaceutical Management (MBA-PM)
2013-2015**



**The IIHMR University, Jaipur
2014**

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CERTIFICATE

This is to certify that Ms. Komal Jain student of Institute of Health Management Research University; Jaipur has undergone summer training at Blue Berry Pharma Advisory from April 04, 2014 to May 27, 2014.

The candidate has successfully carried out the project "Gap Analysis of the top molecules in the leading therapeutic segments using pre-identified criteria" assigned to her during summer training & her approach to study has been sincere, scientific & analytical.

This summer training is in partial fulfillment of the course requirements.

We wish her success in all her future endeavors.

Dr. Seema Mehta
Associate Professor
IIHMR University, Jaipur

Col. (Dr.) Ashok Kaushik
Dean Academics & Student Affairs
IIHMR University, Jaipur



Blue Berry Pharma Advisory

To whomsoever it may concern

This is to certify that Ms. Komal Jain student of IIHMR has undergone summer internship for the period April 4 to May 27, 2014.

During the period Komal has taken keen interest in the project assigned to her, worked very sincerely and demonstrated positive attitude and keen interest to learn.

I wish Komal good luck in her future endeavor.

Subhash Seth
CEO
Blue Berry Pharma Advisory

Acknowledgement

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INTRODUCTION

GAP Analysis

Gap analysis is a formal study of what a business is doing currently and where it wants to go in the future. It has been used as a means of classifying how well a product or solution meets a targeted need or set of requirements.

It consists of listing characteristic factors of the present situation ~~→~~“what is” and listing the factors needed to achieve future objectives ~~→~~“what should be” and then highlighting the gaps that exist and need to be filled by the companies.

About Australia

Australia is a country comprising the mainland of the Australian continent, the island of Tasmania, and numerous smaller islands. It is the world's sixth-largest country by total area. On 1 January 1901, the six colonies federated, forming the Commonwealth of Australia. Since Federation, Australia has maintained a stable liberal democratic political system that functions as a federal parliamentary democracy and constitutional monarchy. The federation comprises six states and several territories. The population of 23.1 million is highly urbanized and heavily concentrated in the eastern states.

Australia is a developed country and one of the wealthiest in the world, with the world's 12th-largest economy. In 2012, Australia had the world's fifth-highest per capita income.

Australia is a wealthy country with a market economy, a relatively high GDP per capita, and a relatively low rate of poverty. With the second-highest

human development index globally, Australia ranks highly in many international comparisons of national performance, such as quality of life, health, education, economic freedom, and the protection of civil liberties and political rights.

Demographics

By 2050, Australia's population is expected to grow by 5 million (an increase of nearly 25% on current numbers) and the proportion aged 75 years or older will have more than doubled (constituting 13.6% of the total population). Ageing populations place considerable strain on health systems. Improvements in medicines, along with life-style improvements, will do much to ease that strain.

Life expectancy

In terms of life expectancy at birth in 2010, Australian males were ranked fifth highest at 79.2 years—0.7 years behind highest ranked Iceland. Australian females were ranked eighth highest at 83.8 years—2.1 years behind highest ranked Japan.

Total disease burden

The leading causes of total burden in 2010 for Australia were coronary heart disease (7.8%), low back pain (7.0%) and Chronic Obstructive Pulmonary Disease COPD (3.4%). This contrasts with the 2003 Australian study where the three leading causes were coronary heart disease (10.0%), anxiety and depression (7.3%) and type II diabetes (5.0%). Back pain was one of the few conditions where the 2010 weights were higher than had been used with earlier studies.

Furthermore, as 10.4% of the low back pain burden is attributed to high body mass, in Australia, increasing levels of obesity will increase the back pain burden. In the 2003 Australian study, COPD was ranked eighth after lung cancer. The higher ranking of COPD is likely to be due to population ageing and long term impact of smoking in older people despite ongoing reductions in smoking prevalence generally—where 65% of COPD in Australia is attributable to tobacco smoking.

Australian Pharmaceutical Market

The pharmaceuticals industry is defined as all those who contribute to the discovery, creation and supply of pharmaceuticals products and services, including prescription medicines and vaccines. The stages of the value chain include discovery research, and basic R&D, through to clinical trials, and then the manufacturing of pharmaceuticals. It includes the originator medicine sector, the generic medicine sector and the medical biotechnology sector.

In 2011 the Australian pharmaceutical industry ranked 15th largest in the world market and largest exporter, with approximately \$4.1Bn of product shipped to over 60 markets worldwide; however we are a net importer with \$10bn of imports annually.

The Australian pharmaceutical industry employed in excess of 44,000 people, and the manufacturing sector consisted of around 150 manufacturers with revenues of \$9.4Bn employing approximately 13,400 people.

As with much of the developed world markets, growth in Australia during the past year continued to grow but, at just 2.3%, growth was slower than in previous years, and the CAGR outlook is 2.6% over the next ten years.

Looking beyond 2012, industry growth will continue to be heavily influenced by the Federal Government and the PBS scheme. There is expected to be a growth in volume but a shrinking in value as government continues to constrain costs and generics continue to grow.

It is likely that local production capacity will continue to decline as competitor capacity and compliance levels in growth economies such as India and China improve. As a result we are likely to see growth in local contract manufacturers, particularly packaging operations. Consequently, employment levels in the industry are expected to decline by around 7% in 2015-2016 compared to 2005-2006 levels.

The Australian clinical trials industry is estimated to generate revenues of \$1bn annually. However, Australia has lost some ground in recent years to developing countries. As the pharmaceuticals industry seeks to cut R&D expenditure, the option to run clinical trials at a lower cost and have access to large patient pools in Asia is proving difficult to counter.

In an effort to ensure Australia's future competitiveness for global trials, the Clinical Trials Action Group was successful in getting key recommendations approved by the Federal Government in 2011. These recommendations will pave the way for speedier approval of new trials and streamline a national ethics approval process to enhance Australia's attractiveness for clinical trials investment.

Australia faces stiff competition from developing countries, particularly in the manufacturing sector. However, it is well positioned to capitalize on opportunities in emerging South-East Asian markets. Additionally, changing attitudes to healthcare and aging populations coupled with ongoing innovation and development in biotechnology present noteworthy opportunities for the industry.

REVIEW OF LITERATURE

The Medicines Australia 2007 industry economic survey provides information on the economic activities of Medicines Australia member companies, as well as insights into the factors that influence development in this country. It indicates the importance of research-based pharmaceutical companies with respect to the broader pharmaceuticals industry in Australia.

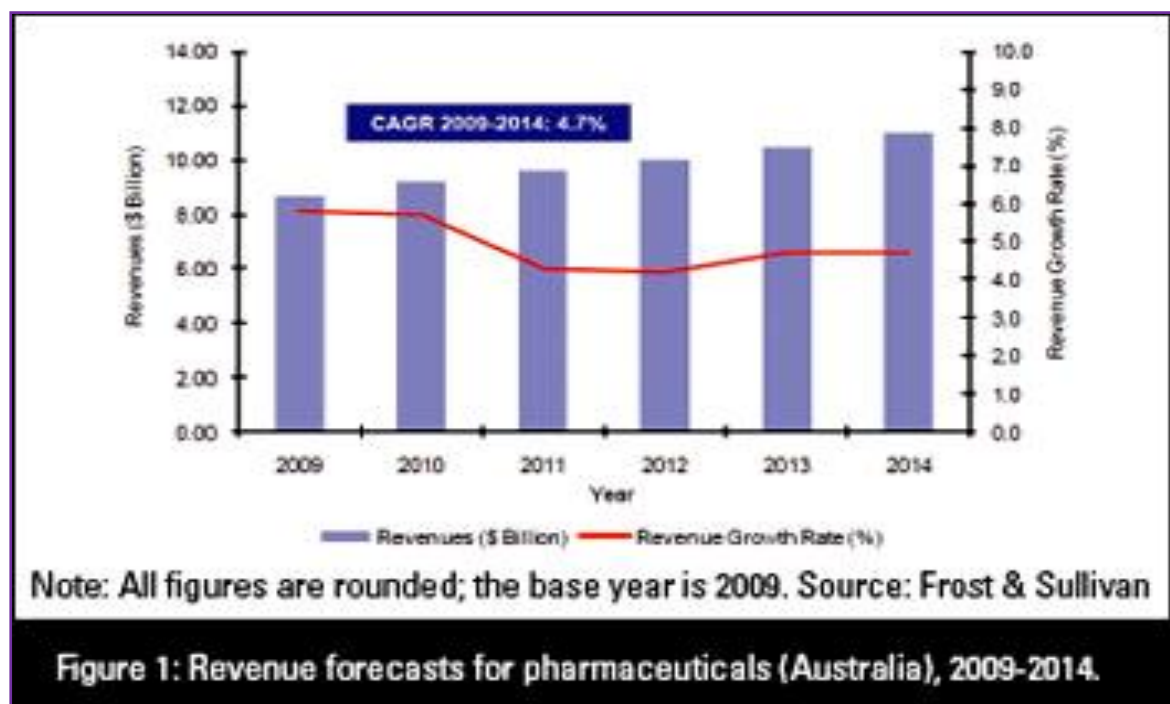
It provides with an outline of companies product portfolios as given by Anatomical Therapeutic Chemical classifications. It looks at an employment trends and workforce distribution within the research based pharmaceutical Industry.

It reviews about the Australia's pharmaceutical companies and the most positive factors affecting their development are the quality of labour, the patent/intellectual property system and the general economic environment. General business environment factors that were considered positives included the general economic environment, political environment, the general R&D environment and Australia's location in the Asia-Pacific.

It supports the notion that Australia generally has a good underlying business environment, and that in a knowledge-based industry like pharmaceuticals it is the quality and skill of the people working in it that are the most important positive success factor. Government policies considered positive were the patent system/intellectual property, policy towards over-the-counter (OTC) medicines, the P3 program, and the drug evaluation and registration system.

Australian Healthcare Market: Therapeutic Segments

The Australian healthcare market earned USD13.24 billion in 2009 and is estimated to earn revenues of USD15.84 billion in 2012 with a CAGR of 6.2 percent. By 2012, the Australian healthcare market is estimated to make up 5 percent of the Asia Pacific healthcare market.



Mature market driven by lifestyle diseases

Australia is a developed nation with increasing levels of lifestyle and age-related diseases. There are requirements of high amounts of pharmaceutical expenditure in areas such as cancer, diabetes, and cardiovascular ailments. One of the most problematic health issues in Australia is the rise of obesity.

In 2009, 18 percent of the pharmaceutical market revenues were spent on the management of obesity and other co-morbidities, such as diabetes and

hypertension. The government requires spending of about USD1.3 billion per year on drug subsidies, awareness campaigns, and other initiatives to lower obesity levels. As a result of these health expenditures, the Australian pharmaceutical market is likely to continue growing and is projected to have a CAGR of 4.7 percent from 2009 to 2014.

Oncology

Government supports for oncology therapeutics and has led to increases in cancer research, diagnosis, and treatment. The Australian antineoplastic and immunomodulating agents market earned revenues of about USD1.1 billion in 2010, with expenditures growing by 8.1 percent per year.

Cardiovascular and metabolic diseases

The Australia cardiovascular market for 2010 earned revenues of approximately USD3.15 billion, with expenditure on pharmaceuticals growing at an average of 2.9 percent annually.

The fastest-growing therapeutic segment in Australia is the diabetes market with an expenditure growing at 13.9 percent per year and earned revenues of about USD950 million in 2010.

Neurological disorders

The fast-growing Australian neurology market earned approximately USD644 million in 2010, with expenditure on pharmaceuticals growing at an average of 13.4 percent annually.

Biologics

Heavy research and development activity into biologics and increased ability to afford high-cost treatments is expected to lead to strong growth in the biologics market.

Need for the Study

- Australian pharmaceutical industry is the 5th largest and worlds largest exporter.It faces stiff competition from developing countries particularly in manufacturing sector.
- Changing attitudes to healthcare and aging populations coupled with on-going innovation and development in biotechnology present net worthy opportunities for the industries.
- Many molecules of various therapeutic segments are going off patent or very few blockbuster drugs are in pipeline.
- Global rationalization is also placing increased competitive pressure on local operations and has resulted in job losses and the closure of R&D and manufacturing operations in Australia.

Objectives

1. To scan the market environment using pre-identified criteria such as sales, units, unit growth, value growth, price.
2. To investigate the different forms of the top molecules in the market.
3. To examine the gap areas of these top molecules.

Study Design

Descriptive study was performed for two months for the various therapeutic segments of Australian pharmaceutical market and gap analysis was done with the help of secondary data such as reports, journals, websites and news .

Methodology

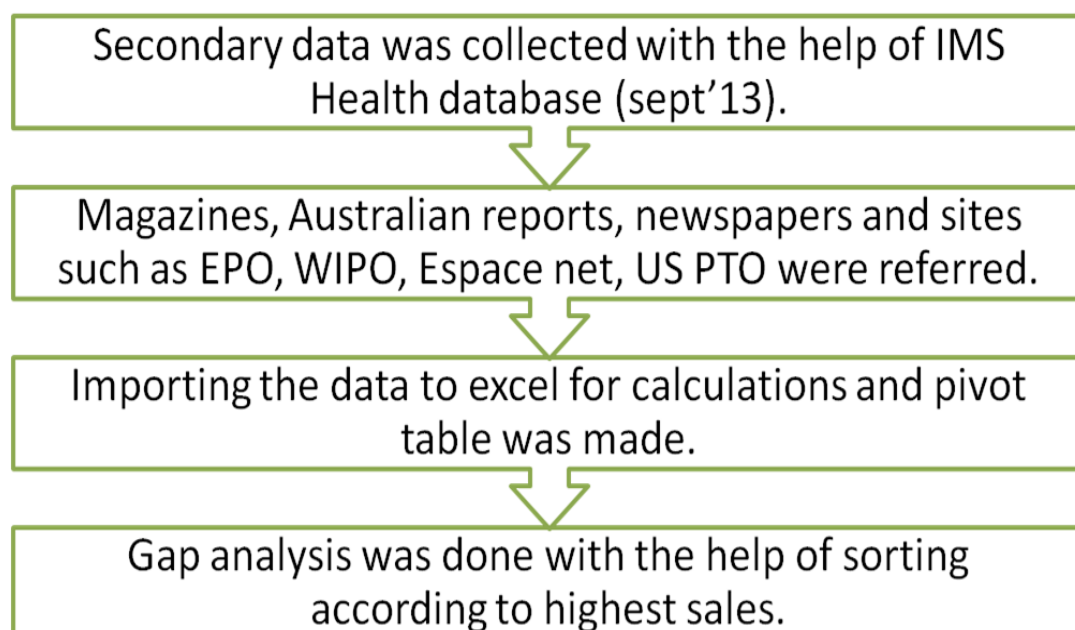


Figure 2: Steps for methodology

Tools used

1

2

3

Analysed on 24th April, 2014.

Sales in Dollars (1000)
Source: IMS

Formulas

1. Price = Sales / Unit
2. Growth value = Sales '13 / Sales '12 - 100
3. Unit Growth = Un '13 / Un '12 - 100
4. Total Sales = Sales '13 + Sales '12 + Sales '11

Therapeutic Segment

Figure 3: The tools used were 1.pivot table 2.sorting&filtering 3.mathematical formulas.

Findings

1. Scanning of the Australian Pharmaceutical Market

Overview of Market Structure and trends	Dynamics of the Molecules	Strategies
• Growth rate of the Industry • Drivers and barriers • Geographical Overview • Regulatory Environment • Socio-economic conditions	• Patent Expiration • Emerging generic drugs • Newer Blockbusters as boosters • Branded Drugs in the pipeline	• Target treatment solutions • Manufacturing process • Introduction of new forms of drugs • R&D in leading therapeutic segments. • New drug delivery systems • Brand Equalisation

Scanning Process:

- Overview of the market structure and trends- The growth rate of the pharmaceutical industry was known.
- Key Drivers and Barriers to Investment in pharmaceuticals R&D, Clinical Trials, and Manufacturing in Australia.

Drivers

The changing nature of medicines and the increasing role of converging technologies in developing a new class of therapeutic products.

R&D – quality of the scientific and medical research base and infrastructure and the strength of the IP protection regime.

Clinical Trials – ability to value add to the global drug development program; investigator initiated clinical research proposals; and world-leading Australian clinicians (and centres of excellence) being sought for global advisory boards.

- Early Stage – quality of the scientific and medical research base and infrastructure, availability of clinical trials sites (suitable for early phase studies) and patients, speed in gaining regulatory approval to conduct the clinical trial.
- Late Stage – quality of the scientific and medical research base and infrastructure, availability of clinical trials sites and clinicians, speed in gaining regulatory approval to conduct the clinical trial, ability to recruit larger patient numbers per site, cost, and growth/value of market in the country and previous conduct of early phase trials with the compound in the country.

Manufacturing – scale, cost, skills, balanced and harmonized IP protection; quality, high value added manufacturing, quality, high level skills and specialized production capability.

Barriers

R&D – lack of critical mass, infrastructure gaps and few globally significant companies from which to develop global centres of discovery R&D.

Clinical Trials – small population, increasing difficulty in identifying and recruiting patients, declining cost competitiveness and declining competitiveness in speed of study start-up.

Manufacturing – not cost competitive against many of Australia's competitors and Australia does not offer the same levels of incentives as other jurisdictions.

Investment Capital – the risk profile associated with biotechnology investments: a stronger track record of success will build confidence in the Australian investment community.

Skills and Education – a skills gap in job ready, highly skilled workers, including expertise in commercialization and business management.

Strategies

Long term strategies should be based on biotech and targeted treatment solutions. Pharma companies should explore further avenues through forward integration with health care and medical equipments. Companies are required to plan to launch health care kiosks offering one-stop-shop services as targeted treatment solutions.

Short term strategies are mainly focused on fighting against pre- and post patent competition. Pharma companies will have to reduce the cost of their operation, manufacturing and research. The implementation of product life cycle management will aim at higher efficiency, risk mitigation and reduced costing.

To reach larger mass through pharmacies, pharmaceutical companies should engage in brand equalization. They have to offer higher incentives to pharmacies to overcome competition.

2. The patent expiry of the molecules having highest sales of the major therapeutic segments was found out.

Patent Expiry	Molecule	Therapeutic Category	Total Sales '11-'13 (USD in 1000)
2019	RANIBIZUMAB	anti-angiogenic	752130
gen	ATORVASTATIN	Antihyperlipidemic	412969
2016	ADALIMUMAB	Antirheumatic	377281
2019	ROSUVASTATIN	Antihyperlipidemic	361345
2018	TIOTROPIUM BROMIDE	anticholinergic COPD	301071
2014	ESOMEPRAZOLE	anti-inflammatory, oncology	280643
2015	PEGFILGRASTIM	Hematopoietic	232117
2018	INFLIXIMAB	Antirheumatic, GI anti-inflammatory	198769
2015	RITUXIMAB	Antineoplastic	193074
gen	ETANERCEPT	Antiarthritic	176423

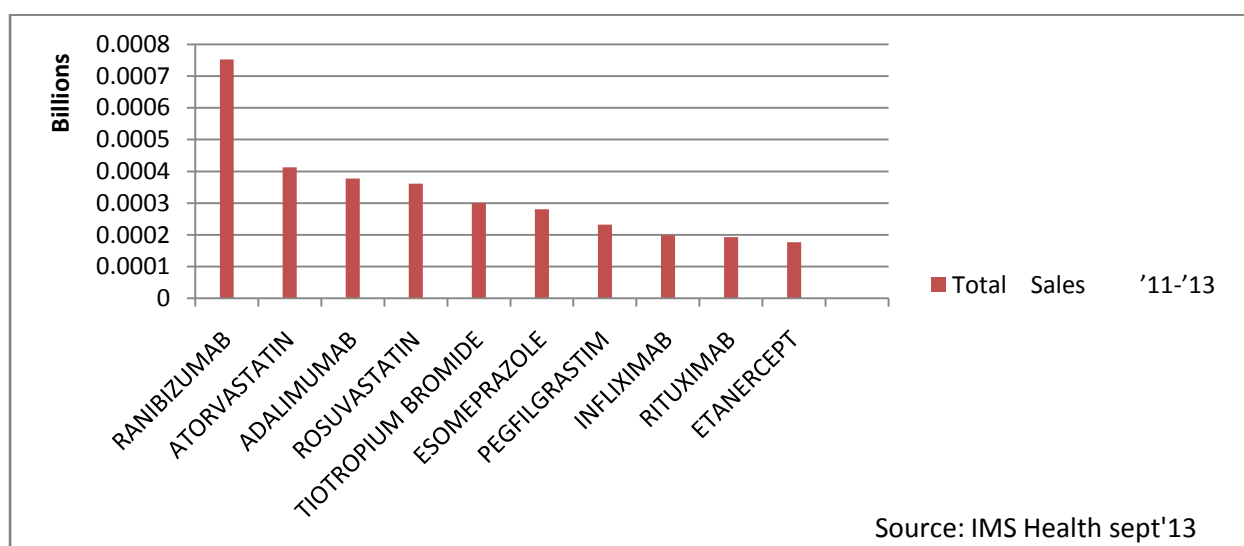


Figure 4: Molecules and its total sales (2011-2013)

3. Bridging the Gap

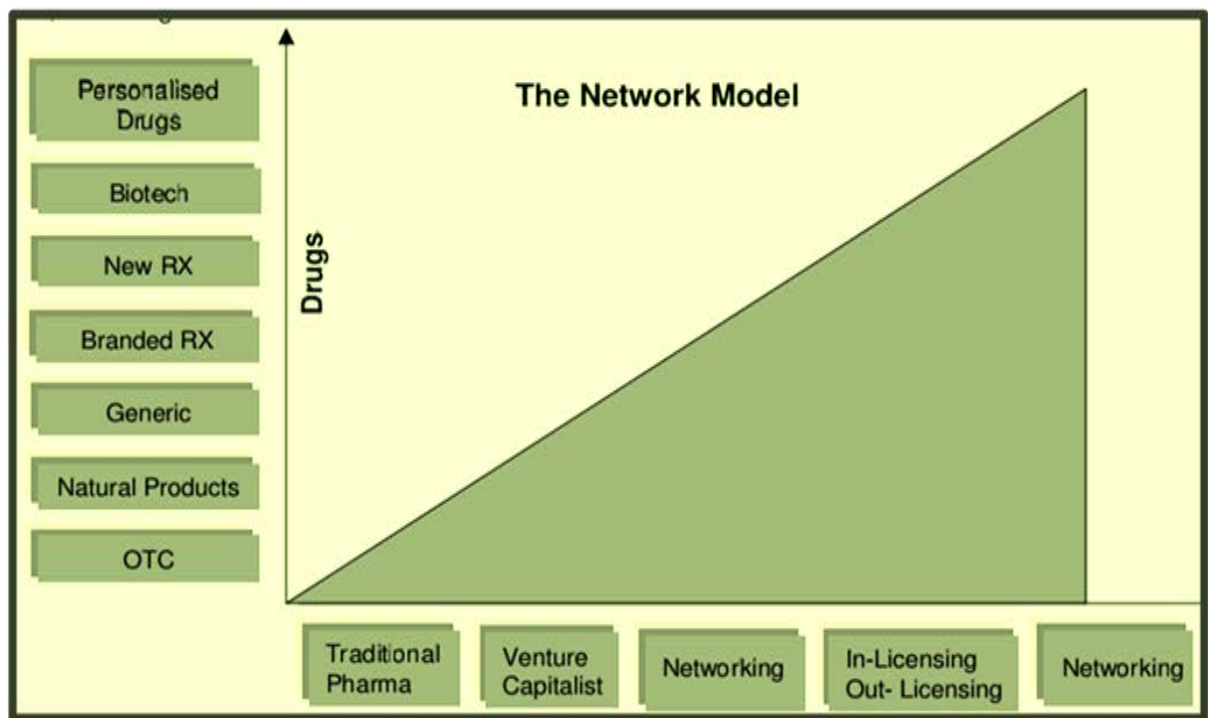


Figure 5: The Network Model “Bridging the Gap”

The pharma network model is based on the network approach and have an in-licensing and out-licensing mechanism, and a network of research companies working on a contract basis.

Pharma companies will have to be more like marketers ,venture capitalists and integrators to bridge the gap between high and low income group companies. This approach will take the pharmaceutical companies to a focused portfolio with higher efficiency, reduced R&D lead time, and cost savings. They will save more money in mergers and acquisitions by entering into early alliances or follow the outsourcing model.

New model pharma companies should adopt the network research model, which works on the basis of alliances and outsourcing to multiple small and

big research organisations and biotech companies. Collaborative R&D will give pharma companies a broader product pipeline with stronger and wider therapeutic focus such as getting into an OTC market or manufacture personalized drugs. Companies will thus leverage technology and benefit from faster time to market their products and cost savings will also be high.

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