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## 1. Foreword

The Indian pharmaceutical industry is the third largest in volume terms and tenth largest in value terms globally. The sector has been witnessing steady growth in the past which has contributed to the country's overall economic growth. A large part of revenues of Indian pharma companies is derived from exports which are expected to touch € 13 billion this year. Besides generics, which is core strength of India, our companies are also focusing on custom manufacturing and bio-pharmaceuticals. The industry is expected to expand at a compound annual growth rate of 23.9 % to reach € 45 billion by 2020. The business friendly policies of the new government have helped Indian companies to look for opportunities across borders.

Germany is the world's fourth largest and Europe's largest economy. Besides automobile, engineering, insurance, IT & telecommunication, Germany has been a significant player in the international pharmaceutical market. German pharma sector is built on the basis of strong R&D as well as legal frame work. Being a highly competitive and developed market, Germany offers the ideal launching pad for Indian pharma companies intending to penetrate the European market. Currently, Germany's major partners in pharma trade are countries in the European Union and USA.

Against this backdrop, I am happy to present the report "German Pharmaceutical Industry – Prospects for Indian Companies" to showcase opportunities available in Germany for Indian pharma companies. This Report was commissioned by the Consulate General of India, Hamburg with the help of a private company M/s ValueWerk, based in Kriftel, Germany. I am sure the report would be useful for all concerned Indian companies, Chambers of Commerce, Ministries & Departments as well as policy makers.

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December 2014



Dr. Vidhu P. Nair  
Consul General



## 2. Executive Summary

Health care and medicine has developed as one of the most important global growth markets especially in advanced economies like Germany. The Pharmaceutical industry in Germany has been a significant global player from the beginning. In 2013, 817 companies were registered as pharmaceutical companies in Germany. In the same year, revenues amounted to € 33.6 billion. The country's pharmaceutical industry employed 110,036 staff in 2013 and exported products valued at € 57.1 billion. In sales terms, Germany is the world's fourth largest pharmaceutical market.

Due to the constant improvement of quality in development and production, German products are popular worldwide. The export figures of the German pharmaceutical industry relative to total production have been growing for years as the table below shows.

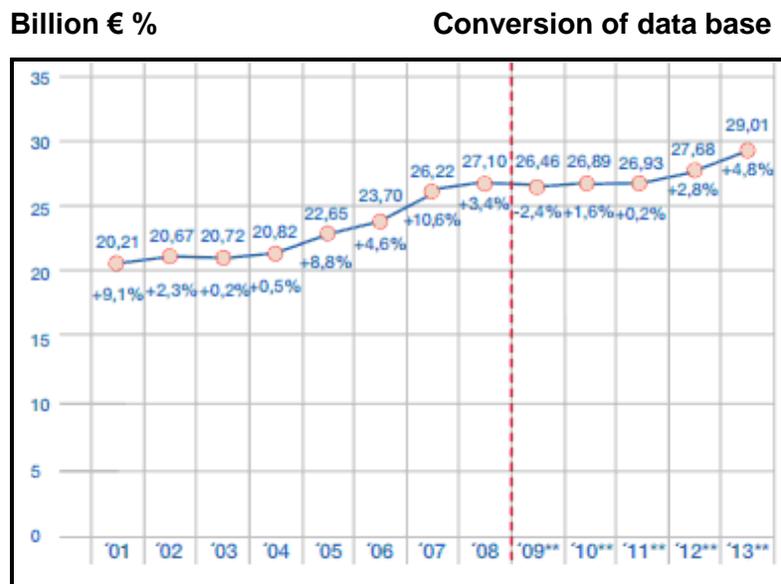
Export and import of pharmaceuticals *				
(In millions of euros and change over the previous year in%)				
Year	Import		Export **	
	Million euros	+/-%	Million euros	+/-%
2002	19,284.83	+60.0	18,835.18	-8.0
2003	19,327.83	+0.2	22,230.11	+18.0
2004	22,221.42	+15.0	28,681.63	+29.0
2005	25,585.17	+15.1	31,758.85	+10.7
2006	28,366.72	+10.9	36,474.52	+14.8
2007	32,706.83	15.3	41,908.34	14.9
2008	34,063.16	+4.1	47,549.32	+13.5
2009	35,552.65	+4.4	47,365.99	-0.4
2010	38,011.26	+6.9	51,133.24	+8.0
2011	37,618.32	-1.0	50,421.52	-1.4
2012	38,186.24	+1.5	54,220.11	+7.5
2013	36,470.92	-4.5	57,123.36	+5.4

\* 21 industry, manufacture of pharmaceutical products. In 2008 a new statistical definition was introduced.

\*\* Based on statistical particularities and various surveys, the production statistics and external trade statistics cannot be compared with each other (Source: BPI)

The innovative work done by companies located in Germany is reflected in their impressive patent figures. Historically, Germany has a very high rate with 272 resident patents filed per million inhabitants (European Average: 107 patents) and with approximately around 30,000 patents granted at the European Patent Office in a year, Germany's share is the largest in the EU. Germany leads the EU in triadic patents (patents registered at the European Patent Office, the United States Patent and Trademark Office, and the Japanese Patent Office). In 2010, some 10,384 patents for pharmaceutical products were registered in Germany.

**Pharmaceutical production \* (2001 – 2013) \*\*** (Production value in billions of Euro, changes compared to the previous year in %)



\* Goods for Production Statistics (GP 21), production of pharmaceutical and similar products.

\*\* As of 2009, the GP 21 (replaced pharmaceutical and similar products) GP244. This new statistical classification prevents a direct comparison with values from previous years. (Source: BPI)

However, the work of pharmaceutical companies in Germany has been greatly hampered in recent years due to legislative measures. Several steps of tightening discount regulations have caused legally mandated manufacturer discounts to triple

since 2005. In addition, discounts have increased substantially in recent years based on individual agreements. Overall, the manufacturer receives only about half of the selling price of a drug. While all other sectors of statutory health insurers reported increased spending last year, expenditures for pharmaceuticals actually decreased.

The main driver behind spending on pharmaceuticals is not the price, which has actually been decreasing for years, but an increase in consumption resulting from an aging society and the availability of new, improved pharmaceutical treatments for severe and life-threatening diseases.

Indian investment in German pharma sector has increased in recent years. Indian pharmaceutical companies are either acquiring firms or starting their own subsidiaries in Germany. Examples include Ranbaxy, Wockhardt, Torrent Pharmaceutical, Ocimum Biosolutions, Biocon, Lupin etc. Dr. Reddy's Laboratories acquired Betapharm GmbH, a generic drugs producer; Biocon acquired 70% stake in German Pharmaceutical company Axicorp GmbH and Manipal AcuNova acquired German CRO ECRON.

As Germany has a large number of technically strong small and medium sized companies, the potential for strategic acquisitions in the pharmaceutical / healthcare sector by Indian companies remains strong. A recent study of the Technical University of Hamburg-Harburg estimates the total volume of Indian investments in Germany at over Euro 3.2 billion.

In this competitive environment, it is important for the Indian Pharmaceutical Industry to focus on the following for a successful market entry strategy:

- **Acquisitions and Joint Ventures:** Indian Pharmaceutical Companies should scout for partners in Germany for getting investment besides acquisition opportunities in Germany with the help of local partners.
- **Play on cost efficiency:** India rates higher than other countries on cost efficiency. This is visibly reflected in the manufacturing costs of US FDA-approved plants in India, wherein the costs are 65 % lower than that in the US and 50 % lower than that in Europe.

- **Have rigorous product selection and commercially relevant evidence:** Indian companies must raise the bar when it comes to products. They should start weeding out programs which do not meet commercial standards without delay. They should be able to control the conversion on metrics and comparators.
- **Medical & Pharmaceutical Trade Shows:** It is important for Indian Pharma companies to represent themselves at International Trade Fairs to meet prospective business partners, investors and look for opportunities in partnering and outsourcing.
- **Branding & Marketing presence:** The pharma sector is heavily influenced by the statute and credibility of the players and one often hears huge scandals involving product recalls which can doom the company. There needs to be a significant marketing and branding strategy to ensure building up of trust in the local market.
- **Investing in local presence:** It is imperative for an Indian company to have a local presence in terms of a branch office. Although it is better to have a large setup, even a small skeletal setup will go a long way in ensuring hands on responsibilities as well as business contacts in the local market.
- **Utilization of favorable loans and subsidies provided by the German government:** In order to support the industry as well as to support employment and innovation, the German government offers several incentives for investment in this sector both at the federal level as well as the state level. Further, the EU often funds specific programs as long as it is based in the European Union including Germany.
- **Insolvent businesses:** Many pharma businesses in Germany are struggling due to lack of succession plans, inability to tap global markets or shortage of qualified staff to fulfill resource requirements. However, many of these companies hold world class manufacturing capabilities as well as patents in specific niche areas which can be interesting for Indian companies to take over at a very reasonable price.

### 3. Overview of the German Pharmaceutical Industry

Germany's drug market is the fourth largest worldwide after the United States, Japan and China. However, the German government which is a large player/consumer/investor remains committed to its fiscal austerity program and to further spending cuts. Hence market consolidation is expected to continue, and drug prices have been under pressure from de-reimbursement, fixed-level drug pricing and referencing pricing schemes. Between 2011 and 2015, the market is projected to grow annually at 3%, with the fastest growth in the specialized hospital market for new and expensive pharmaceuticals. The statutory health insurance system accounts for about 80% of the market, with tight reimbursement rules, greater use of generics and downward pressure on generic prices due to the rebate system and the full VAT of 19% levied on drug sales. Opportunities also exist for local production, research and acquisition of German drug firms.

Despite sluggish market growth in recent years and increasing competition from generic drug manufacturers as a result of patent expiration, Germany remains an attractive export market to innovative Indian drug makers. Recent sales growth has been for drugs for acute conditions such as cancer, rheumatoid arthritis and multiple sclerosis; as well as chronic conditions such as cardiovascular diseases, diabetes etc. besides preventive medicine. Drugs for rare diseases, the so-called Orphan Drugs, with market exclusivity for 10 years in the European Union, have good market potential as also bio-based medication, personalized medicines and bio-similars.

Major suppliers pharmaceuticals *to Germany (in million EUR)					
	2009	2010	2011	2012	2013
Switzerland	4,845.13	5,443.70	6,374.50	7,007.74	7,449.89
USA	7,193.84	6,253.57	5,728.23	7,110.13	5,729.14
Netherlands	1,182.51	1,954.97	4,127.49	4,415.10	5,040.24
France	1,741.94	2,331.83	1,754.11	2,013.44	2,197.79
Italy	1,544.32	1,702.05	1,792.42	1,975.45	2,122.91
Belgium	1,292.34	1,487.43	1,822.54	1,514.20	1,983.70
Ireland **	7,934.95	4,751.54	4,453.31	2,880.42	1,934.73
Great Britain	2,299.43	2,549.45	3,313.73	2,990.15	1,775.78
Sweden	1,104.91	1,217.70	1,035.44	1,143.18	1,319.79
Spain	1,205.72	2,479.95	1,023.40	1,149.15	971.83
East	5,203.30	5,798.47	5,993.14	5,784.84	5,925.11
Total	35,552.63	38,011.25	37,620.32	38,186.24	36,470.92

The main customers pharmaceuticals **from Germany (in million EUR)					
	2009	2010	2011	2012	2013
USA	5,841.38	4,979.74	5,445.32	8,157.45	8,455.29
Netherlands	4,423.55	4,553.10	4,474.74	4,537.49	4,452.43
Great Britain	2,440.71	2,770.38	2,421.35	3,174.74	5,142.40
Switzerland	2,845.12	2,818.90	3,221.24	3,340.33	3,479.37
Belgium **	10,918.27	10,495.80	7,531.28	4,544.95	3,571.14
France	2,255.97	2,525.98	2,752.75	3,594.47	3,384.32
Italy	2,192.40	2,445.54	2,484.00	2,530.89	2,211.14
South Korea	984.30	1,390.50	1,424.93	1,842.74	2,101.54
Japan	1,151.52	1,142.35	1,324.45	1,419.03	1,828.15
Austria	1,252.11	1,458.74	1,551.04	1,538.89	1,425.41
East	13,020.45	14,512.24	15,144.23	17,334.92	18,449.95
Total	47,365.97	51,133.24	50,423.36	54,220.11	57,123.36

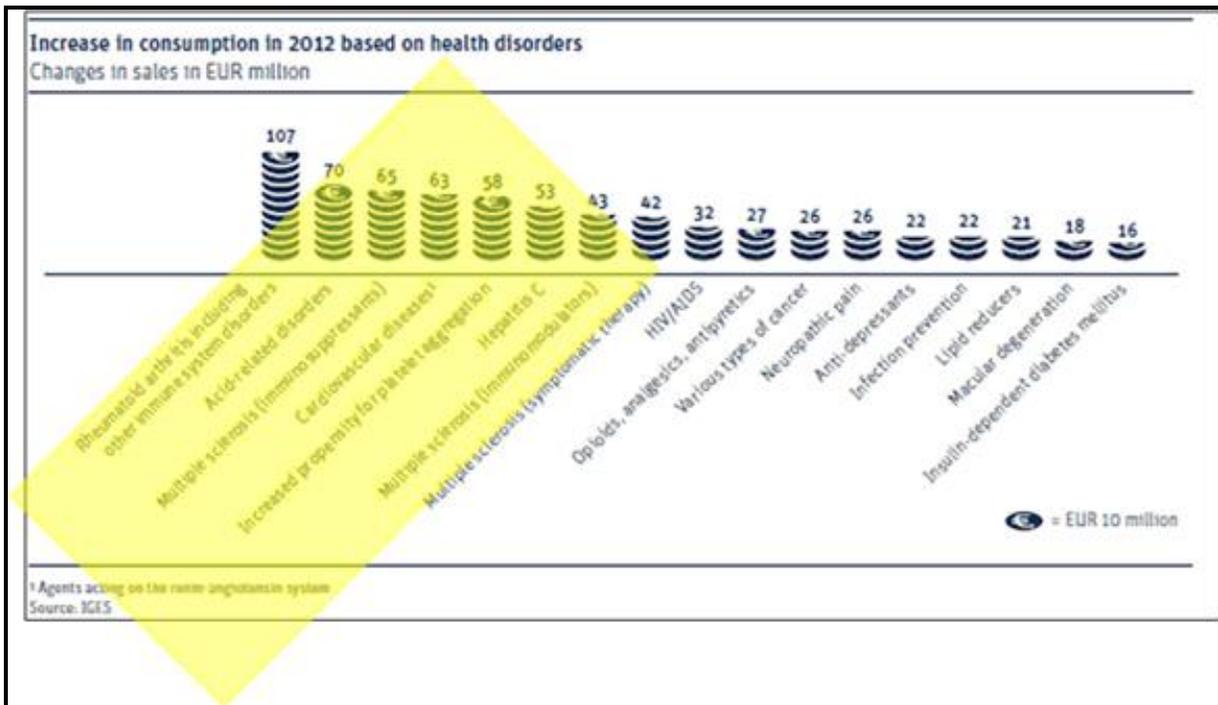
\* 21 industry, manufacture of Pharmaceutical products. In 2008 a new statistical definition introduced. The production of Pharmaceutical products is now under WZ 21 (previously WZ 24.4). (please refer to German Classification of Economic Activities [www.destatis.de](http://www.destatis.de))

\*\* The exceptional level of exports by the year 2011 has been declared the VCI with special effects. Source: BPI

As it is seen from the above data, Europe and the USA are the biggest suppliers of pharmaceuticals to the Germany with the Asian region still a long way off from breaking in. This in itself is an opportunity for Indian companies as Indians could have the first mover advantage. Further thanks to the reputation of Indian IT, we enjoy an edge over China in terms of credibility in this critical sector.

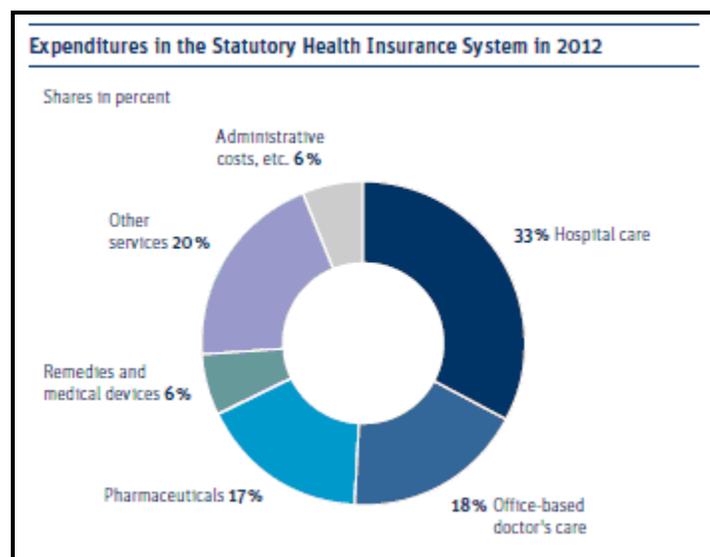
Based on Indicative sales figures we are of the opinion that the most attractive areas, one can derive that the most attractive areas of investment in the industry are:

1. Anti-TNF Preparations
2. Anti-Depressants/Mood Stabilizers
3. Anti Epileptics
4. Angio Tensin II Antagonists
5. Anti Neo Plastics

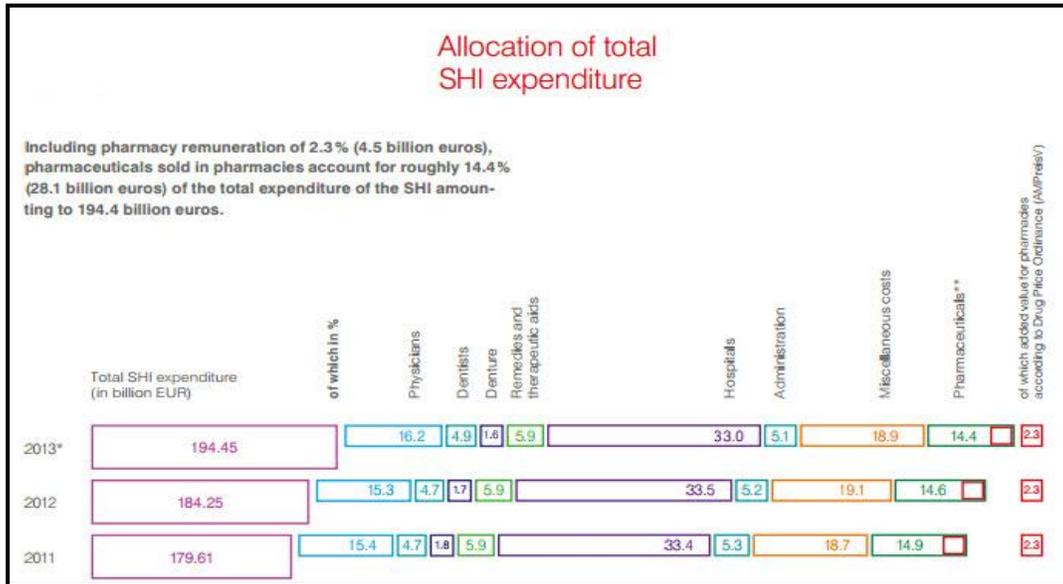


Similarly the highest increase in consumption is derived from:

1. Rheumatoid Arthritis including other immune systems disorders
2. Acid related disorders
3. Multiple Sclerosis (immunosuppressants, modulators and symptomatic therapy)
4. Cardiovascular diseases
5. Increased propensity for platelet aggregation
6. Hepatitis C



A third of SHI expenditures, € 62.5 billion of a total of € 190 billion, are spent on hospital treatment. Together, expenditures on care by doctors (€ 34.5 billion; 18%) and for pharmaceuticals (€ 31 billion; 17 %) make up another third, with € 9.6 billion spent on administrative costs. Increases in mandatory manufacturer discounts resulted in a 2.2 % decrease in expenditures for pharmaceuticals in 2013 compared to 2010. The 2013 SHI figures are shown below.

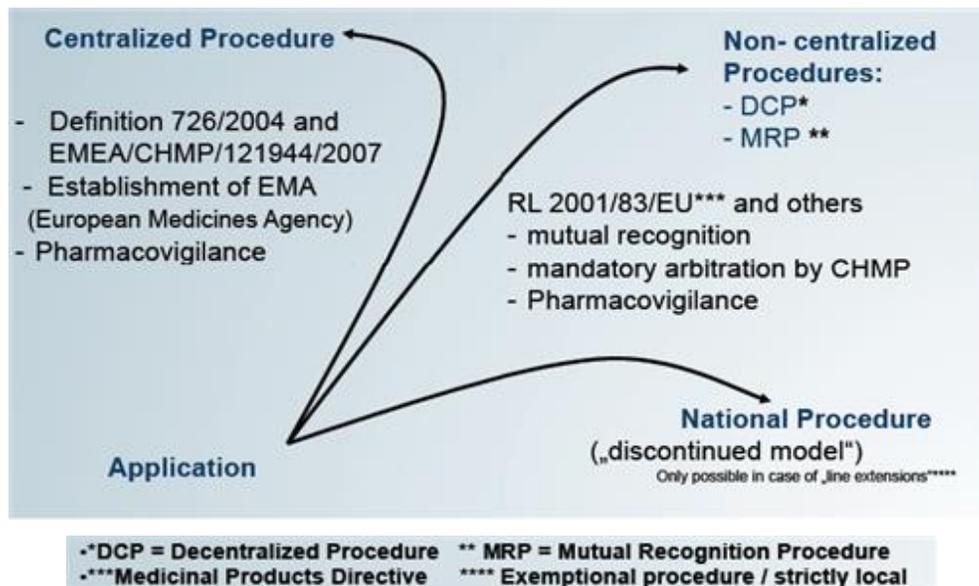


List of top pharmaceutical companies in Germany	
Boehringer Ingelheim	Merck KGaA
Bayer HealthCare	Noxxon Pharma
Bayer Schering	Roche
Fresenius	Sandoz
jenapharm	Tegenero
Jerini	Midas Pharma
Medac	Venus Pharma
Merz Pharma	3B Pharmaceuticals
temmler	Schwabe Pharma
Ratiopharm	Hexal AG

One can observe that many of the companies above are not “German” but from Switzerland, France, etc and many more companies are in the process of setting up German operations. Further, it is interesting to note that Venus Pharma is owned by an Indian company and is very successful in Germany.

## 4. Germany's Regulatory Environment

### 4.1 Overview of the Regulatory Procedures



In the European Union (EU), medicines can be authorized by the centralized authorization procedure or national authorization procedures.

#### Centralized authorization procedure

The European Medicines Agency is responsible for the centralized authorization procedure for human and veterinary medicines. This procedure results in a single marketing authorization that is valid in all EU countries, as well as in the European Economic Area (EEA) countries like Iceland, Liechtenstein and Norway.

The centralized procedure is compulsory for:

- Human medicines for the treatment of Human Immunodeficiency Virus (HIV) or Acquired Immune Deficiency Syndrome (AIDS), cancer, diabetes, neurodegenerative diseases, auto-immune and other immune dysfunctions, and viral diseases;
- Veterinary medicines for use as growth or yield enhancers;
- Medicines derived from biotechnology processes, such as genetic engineering;
- Advanced-therapy medicines, such as gene-therapy, somatic cell-therapy or tissue-engineered medicines;

- Officially designated 'orphan medicines' (medicines used for rare human diseases).

For medicines that do not fall within these categories, companies have the option of submitting an application for a centralized marketing authorization to the Agency. This is possible for medicines:

- That are significant therapeutic, scientific or technical innovations, or;
- Whose authorization would be in the interest of public or animal health.

Applications through the centralized procedure are submitted directly to the Agency. Evaluation by the Agency's Scientific committees takes up to 210 active days plus 'clock stops', at the end of which the committee adopts an opinion on whether the medicine should be marketed or not. This opinion is then transmitted to the European Commission, which has the ultimate authority for granting marketing authorizations in the EU. Once a marketing authorization has been granted, the marketing-authorization holder can legally begin to market the medicine in all EEA countries.

### **National authorization procedures**

Each EU Member State has its own national authorization procedures for the authorization, within their own territory, of medicines that fall outside the scope of the centralized procedure. For Germany, Federal Institute for Drugs and Medical Devices, Paul Ehrlich Institute and Federal Office of Consumer Protection and Food Safety are the National competent authorities.

There are also two possible routes available to companies for the authorization of these medicines in several countries simultaneously:

- **Decentralized procedure**

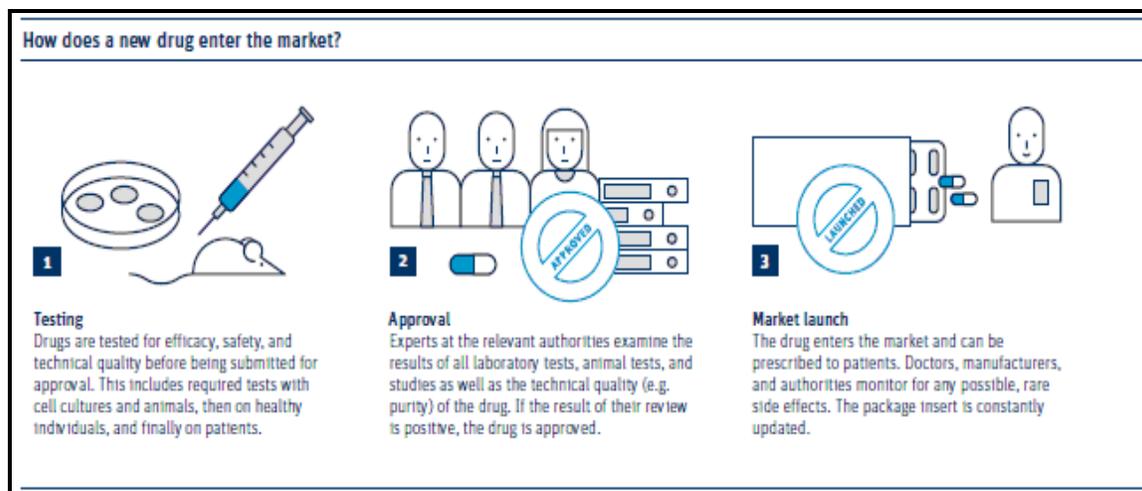
Companies can apply for the simultaneous authorization of a medicine in more than one EU country if it has not yet been authorized in any EU country and it does not fall within the mandatory scope of the centralized procedure.

- **Mutual-recognition procedure**

Companies that have a medicine authorized in one EU Member State can apply for this authorization to be recognized in other EU countries.

#### 4.2 Overview of the new drug entry process in German market

A new drug approval is a two phase process - the first phase of clinical trials and the second of marketing authorization of drug. Firstly, non-clinical studies of a drug are completed to ensure efficacy and safety, and then application for conduct of clinical trials is submitted to the competent authority of the concerned country. The clinical trials are performed to ensure the efficacy, safety and optimizing the dose of drug in human beings. After the completion of clinical studies of the drug, an application to the agency for approval of drug for marketing is submitted. The agency will review the application and approve the drug for marketing only if the drug is found to be safe and effective in human being or the drug have more desirable effect as compared to adverse effect.



In Germany a clinical trial must not be started before it is authorized by the competent federal authority. Depending on the type of investigational product two higher federal authorities with different responsibilities exist in Germany whose competences are regulated by the German Medicines Act (Arzneimittelgesetz, AMG). The Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM) is responsible for clinical investigations of drugs, medical devices and performance evaluations of some in vitro diagnostic agents. The Paul-Ehrlich-Institute (PEI) is responsible for performance evaluations of high risk in vitro diagnostic agents like vaccines, sera and blood and plasma derived products.

BfArM is an independent higher federal authority within the Federal Ministry of Health. It is the successor to the Institute for Drugs (Institut für Arzneimittel) founded in July 1975 as part of the now dissolved Federal Health Office (Bundesgesundheitsamt, BGA). One of the main tasks of the BfArM is the authorization of finalized medicinal products on the basis of the German Medicines Act (Arzneimittelgesetz, AMG). In the course of these licensing procedures, the authority reviews the proof of efficacy, safety, and adequate pharmaceutical quality of the finalized medicinal products. The authorization of finalized medicinal products includes the approval of requests for authorization of a clinical trial by a sponsor or authorized CRO.

The request for authorization of a clinical trial has to be made in writing. The BfArM's authorization is subsequently assumed, unless it has, within 30 days, stated reasons for denying its consent to a clinical trial. Furthermore, the Federal Institute for Drugs and Medical Devices has to be notified about the end of a trial within 90 days and about interceptions or an interruption within 15 days.

## **5. German Pharmaceutical Industry analysis**

Germany offers the perfect location for Research, Production and Sales. It benefits from internationally renowned scientists, world-class research and immediate market access to Pharmaceuticals.

### **5.1. Strengths of the German Pharmaceutical Market**

- **Strong Export Market:** Since the 1990s, Germany has been able to maintain its position as an important global production location for pharmaceutical products.

Germany is the ideal location for internationally operating players as the export oriented culture is fostered at every level of the government, especially through various support programs. Further, Germany is in the center of Europe and is excellently connected to the Central and East European markets making it a hub of production and distribution

- **Growing Bio-Pharmaceuticals Sector:** Bio-Pharmaceuticals is an important part of the pharma sector in Germany. In 2012, 142 Bio Pharmaceuticals were licensed in Germany. Sales of Bio Pharmaceuticals on the German pharmaceuticals market grew by 10 % to EUR 6 billion and as a result, accounted for 21 % of sales in the German pharmaceuticals market as a whole
- **Stable Healthcare Consumer Market:** In 2011, Germany ranked fourth internationally in terms of GDP health spending (11.3 %). Around EUR 161 billion in funding was set aside for the statutory health insurance sector and a foreign investor can look into tapping the domestic market as well especially the OTC market.
- **Highly Trained Labor Force:** Highly skilled and specialized employees are a key feature of the German labor market and will remain so. Nearly 50 national universities offer life sciences and biomedical engineering programs. Labor cost increases have been the lowest in Europe in recent years, with a modest annual increase rate of around 2 %. German productivity rates are almost 10 % greater than the average of the EU's 15 core national economies.
- **Sound and Secure Legal Framework:** According to the World Economic Forum (WEF), Germany is one of the world's best locations in terms of planning and operating security. This is especially relevant for pharma in terms of patent related legislation.
- **Herbal Medicines/ Ayurveda:** Herbal remedies represent an important share of the German pharmaceutical market. Though the herbal/traditional products posted 1% decline in current value terms in 2013, performances of the different categories varied, with herbal/ traditional calming and sleeping products posting a current value gain of 2% and herbal/traditional digestive remedies posting a decline of 3%.

## 5.2. Challenges in the German Pharmaceutical Market

- **Commoditization combined with extensive reforms in both regulated and unregulated markets is increasing pressure on prices:** Although healthcare reforms have boosted sales of generics in recent years, government is looking to reduce their generic drug expenses. More on more countries are witnessing a dramatic shift in their business model as players become key stakeholders through implementation of tenders.
- **Product portfolios are becoming increasingly complex:** The share of hard - to make and specialized drugs going off patent - including drug/ device combinations, sterile injectibles and biologics - will increase. By 2016, 8 of the top 10 Pharmaceutical drugs will be biologics.
- **Managing the business while maintaining a lean structure and striving for cost leadership has become more complex:** The top two global players each have up to 1,000 compounds in the market and even more products in the pipeline covering oral solids, bio-similars, respiratory, sterile injectibles and patches
- **Quality control in manufacturing remains challenging:** 1.4% of batches are rejected for generics companies as compared with 0.4% for originators and there are 72 deviations per 1,000 batches for generics players as compared with 53 of originators. In comparison with other industries, generics players also have clear room to improve their obsolescence rates and service levels.
- **New players are intensifying competition:** New entrants in the market include electronics companies such as Samsung and Fuji in certain segments of generics, as well as originators such as Abbott and Sanofi.

## 6. German Pharmaceutical Industry trade forecast

Pharmaceutical products showed strong performance in 2013 with output growth of 5.3% in real terms. In the current year, output jumped again in the first eight months with a real increase of 6.8% on the pre-year reading. After a 1.3 % point rise in capacity

utilization in 2013, the positive trend has continued unbroken in 2014. In Q4, capacity utilization hit 86.4%, noticeably outstripping the long-term average.

Unlike in the prior years, incoming domestic and foreign orders moved in the same direction in 2013. Nonetheless, growth of the pharmaceuticals industry continues to be driven by exports (export ratio in 2013: 69%). Total order intake was up 3% in 2013, with domestic orders rising by 2.2% and foreign orders by 3.4%. The positive climate has resulted in very robust order growth again so far in 2014 (foreign: +9.6% YoY; domestic: +6.6%). For 2014 as a whole and for the coming year positive impulses are expected from the home market and from abroad. The foreign growth in particular results from strong demand from non EMU countries. The improvement in the economy there, in the US in particular, is likely to support the growth of Germany's pharmaceuticals industry. Increasing demand for healthcare in Asia and Latin America could generate additional orders for the industry.

Nonetheless, the domestic market remains confronted with a challenging regulatory environment. This is evidenced above all by this year's decision to extend the price moratorium for pharmaceuticals until 2017, which is aimed at preventing an increase in the cost of supplying drugs and medications. Producer prices in the sector have thus been trending down for years.

All in all, real pharmaceutical output should grow by at least 4% this year. The arguments against higher growth are the increases in macroeconomic risks and the shape of the IFO business expectations, which have trended downwards during the last few months and were very volatile of late. Further existing burdens are the regulations governing new product launches and the benefit assessment of drugs on the basis of the Act for the Restructuring of the Pharmaceutical Market (AMNOG). For the coming year DBR forecasts a lower rate of output growth (+2%) than in 2014, and a continuation of the positive fundamental trends (demographics, greater health consciousness). However, production is very volatile in the course of the year, so positive and negative surprises are possible.

## **7. Overview of the Indian Pharmaceutical Industry**

The Indian Pharmaceutical Market (IPM) is valued at ₹ 72,069 Crore in 2013 (€ 9241.3 million) as against ₹ 65,654 Crore (€ 8446.3 million) in 2012. It has experienced a slowdown with growth going down to 9.8% from 16.6% for the year 2012. There has

been a slowdown in the growth of the top Indian as well as multinational companies. However, the slowdown is more prominent in MNCs than in the Indian companies. In 2012, the top five MNCs had grown at the rate of 16% which dropped down to 7% in 2013.

The contribution of chronic therapies (cardio, gastro, CNS and anti-diabetic) to the IPM has gone up from 27% in 2010 to 30% in 2013. Chronic therapies have outperformed the market for the past four years and are growing at a rate of 14%, faster than the acute therapies (anti-infectives, respiratory, pain and gynae) which grew at 9.6%. This essentially translated in an overall slowdown in 2013.

Though Indian pharma industry has remained shock proof to recession in the past, companies are facing the heat of slowing economic growth at present. The domestic economy continued to grow at a subdued GDP growth rate of 4.7% during first three quarters of 2013 as against 5.2% in the previous year period. The cumulative sale for first nine months of 2013 grew by just 9% against 17.4% in the previous year. Both, domestic and export led demand contributed towards the robust performance of the sector. Lower cost of production and availability of highly skilled labor pool at low cost has helped Indian pharmaceutical companies to innovate and develop generic substitutes of patented drugs at a fraction of cost incurred in developed markets.

Moreover, the industry is facing stringent regulatory and quality norms both at global and domestic fronts. Increasing government intervention is expected to impact industry's performance in the near term; however such interventions are necessary to bring India at par with global standards.

The number of new products launched has gone down from approximately 1900 in 2010 to approximately 1700 in 2012. Of all the new launches as of April 2013, the maximum were anti-infectives (468), pain- analgesics (435) and gastro (389) therapies. The implementation of the National Pharmaceutical Pricing Policy 2012 by the government of India has resulted in margins erosion from 20% and 10% to 16% and 8% for retailers and stockists respectively. This decrease in the margins led to a significant uncertainty among many stockists regarding the feasibility of staying in business due to lower profitability post the margin reduction.

In addition to growth challenges, Indian pharmaceutical industry is currently grappling with a number of issues like delays in clinical trial approvals, uncertainties over the FDI

policy, the new pricing policy, a uniform code for sales and marketing practices and compulsory licensing, all of which need a speedy resolution. The industry is also facing stricter regulations on manufacturing and quality practices in the domestic as well as the international markets. Besides concerns have been expressed about the approval of drugs without clinical trials, unethical practices in clinical trials and payment of compensation to patients or kin in the event of adverse events in clinical trials. The Government of India has responded to these concerns by bringing in additional oversight mechanisms for clinical trials and notifying new rules for clinical trials. Approvals for clinical trials in India however have slowed down considerably.

Another critical concern for the pharmaceutical and life sciences companies is to create a compliance program that encapsulates the local as well as the global regulations guiding operations and practices of the pharmaceutical and life sciences industry. Focusing on the Medical Council of India's code (MCI), the draft Uniform Code for Pharmaceutical Marketing Practices (UCPMP) and the Organisation of Pharmaceutical Producers of India (OPPI) code, as applicable can help companies fix the loopholes in their current compliance program and make it more robust. Further, emerging technologies called SMAC: Social networking, Mobile computing, Analytics and Cloud computing, are likely to play a crucial role in addressing these challenges, improving operational efficiencies and amplifying the performance of the pharmaceuticals companies. Though each of these technologies has a unique impact, they also complement each other in order to drive business transformation. These technologies jointly foster innovation through new ways of product development, customer service and interaction and partnerships, thereby creating value and stimulating success.

India has had an efficient pharmaceutical industry which has been making affordable drugs not just for the Indian markets but has also been exporting them to the world however off late it has been facing rising FDA scrutiny for quality. US FDA has increased its scrutiny on the quality coming from India located manufacturing plants. Indian companies will have to raise their compliance to US FDA regulations as their major share of exports go to the US market.

### **7.1. Industry trend and developments**

- US \$ 14.7 billion (€ 11.83 billion ) export market as of 2012-2013
- Government unveiled 'Pharma Vision 2020' aimed at making India a global leader in end-to-end drug manufacture

- Reduced approval time for new facilities to boost investments
- The government plans to allocate US \$ 70 million (€ 56.3 million) for local players to develop bio-similars
- India accounts for over 10 % of global pharmaceutical production of over 60,000 generic brands across 60 therapeutic categories
- The trade surplus in the pharma sector is likely to expand to US \$ 16.5 billion (€ 13.3 billion) by 2016
- Pharmaceuticals industry sales stood at US \$ 15.6 billion (€ 12.6 billion) during 2011
- It is forecasted to double in five years, reaching US \$ 35.9 billion (€ 28.9 billion) by 2016
- Domestic market size is currently valued at about US \$ 12.26 billion (€ 9.9 billion); the segment is set for double-digit growth over the next five years
- From US \$ 200 million (€ 161 million) in 2008, revenues for 2013 were US \$ 12 billion (€ 9.7 billion)
- The Indian pharmaceuticals market is expected to expand at a CAGR of 23.9 % to reach US \$ 55 billion (€ 44 billion) by 2020. (IBEF report)
- India manufactures more than 400 different APIs and is expected to supplant Italy as the second largest producer of APIs globally
- Pharma exports from India are forecasted to increase more than two folds over the next five years
- Alimentary drugs command the largest share (over 13 %) in the Indian Pharma market
- The cardiovascular segment represents 10 % of the market share; its contribution is likely to rise due to the growing number of cardiac cases in India
- Japan accounts for over 50 % of pharmaceutical sales in Asia-Pacific, followed by China which is a distant second with 19 %
- India, with a little over 10 % market share, ranks third by market size

## **7.2. Indian Pharmaceutical Industry forecast**

The Indian pharma market is changing, and the need to service this market is changing drastically. To sustain the robust growth in future, the companies will have to adapt to new business models to serve their customers better. The companies that will reach patients faster and develop innovative ideas to cater to the changing needs of patient will succeed in the near future.

In order to sustain a robust growth rate of 15 to 20%, companies will have to rethink the way they do business. Over the years, pharma companies have grown inorganically through acquisitions. But due to higher valuations seen in the sector over the last two years, they have been exploring newer methods of partnerships such as joint ventures and licensing of innovator products and technologies. Companies are focusing on improving operational efficiencies and have also used the traditional growth levers to drive growth. These initiatives have yielded results but some have also brought in new set of challenges, which companies will have to address for achieving profitable and sustainable growth. For instance, companies have traditionally increased the field force to penetrate newer markets. This has helped companies to expand, sometimes below expectations. As increase in field force has not yielded expected productivity, it is becoming difficult for the companies to derive a fair return on investment due to reduced profitability and higher cost. For example, from 2008 to 2014, the sales of top pharma companies grew by approximately 16.1% and the number of sales representatives increased by almost 11 % while the productivity per representative grew only by 4.5 %. Companies have looked at portfolio expansion for gaining a larger share in the Indian market. However, this has not only led to a wider portfolio, but also a large proportion of more than 80 to 90% of brands not even crossing the ₹ 1 Crore (US \$ 0.16 million ; € 0.13 million) mark.

To register robust growth in the future companies need to think through the following:

- **Higher volumes through lower prices:** As we have seen that chronic diseases are setting in early, a large majority of the population will be still working, and this is going to increase the burden on the patients. Pharma of 'penetration strategy' working successfully would be determined by 'higher volumes through lower prices. Some MNCS have looked at differential pricing while launching their global drugs in India.
- **Collaboration with new stakeholders in the super-specialty and specialty segments:** Companies will have to work closely with key stakeholders like the payers and providers to improve patient compliance especially in specialty and super-specialty segments. In a country like India, the diagnosis rate is low and a compliance rate is lower in the treatment of almost all chronic diseases. Creating awareness about the disease and its implications will improve the diagnosis rate

and accelerated efforts from companies through key stakeholders will improve compliance drastically. Improved compliance will dramatically increase sales of some drugs and, in turn, will drive growth of companies.

- **Customizing for Indian market:** Indian market is different from the developed markets in terms of epidemiology, awareness, treatment protocols, and compliance and, above all, pricing: The innovator companies when launching new products will have to customize their strategies for the Indian market in order to make the product accessible and affordable to the masses.
- **Shifting towards prevention:** The market will change from treatment to prevention, like other evolved markets. Indian companies will have to look into the healthcare management, work with various stakeholders, and use advanced technology to reach out to more patients. These include use of information and communication technologies such as mobile phones.
- **Launching patient programs:** In India the awareness and literacy rates are on the rise. The patient is more informed, aware and well read than before. As a result, the treatment modality is changing from doctors to self care. When the treatment is shifting from hospital to primary care or from doctor to self care, there is a tremendous need to connect directly with the patient and pass more information to them. Patients will require new services such as home delivery. Companies will have to come up with innovative ideas to service these patients which, in turn, will increase the patient base and boost sales and growth.
- **Realigning field force strategy:** In order to improve sales force productivity, companies will have to revisit the field force strategy, make changes if required and build in new skill-sets. For instance, they will need to provide employees skill sets such as serving patients as customers, look for penetration into newer geographies by piggy-riding on the experience of other industries like FMCG. Thus, in this changing market scenario, the companies will have to change their strategies, adopt newer business models, modify or re-visit the old models and look for incremental growth from areas, wherever possible.

### 7.3. Indian Pharmaceutical Industry SWOT analysis

#### Strengths

- Low cost of innovation, manufacturing and operations
- Low cost of skilled manpower and proven track record in design of high technology manufacturing devices
- Significant expertise (Human Resources) availability

### **Weaknesses**

- Stringent pricing regulations affecting the profitability of pharma companies
- Presence of more unorganized players versus the organized ones, resulting in an increasingly competitive environment, characterized by stiff price competition
- Poor R&D Infrastructure
- Poor Industry - Academia linkage
- Unclear Regulatory reforms

### **Opportunities**

- Opening of the health insurance sector and increase in per capita income - the growth drivers for the pharmaceutical industry
- India, a potentially preferred global outsourcing hub for pharmaceutical products due to low cost of skilled labor
- According to various studies, India is among the leaders in the clinical trial market.
- Market would open up for the production of high-end drugs in India due to the growing demand.
- Immense opportunities for pharma companies to tap the rural market in India

### **Threats**

- Other low-cost countries such as China and Israel affecting outsourcing demand for Indian pharmaceutical products
- Entry of foreign players (well equipped technology-based products) into the Indian market
- Increasing non- tariff barriers and stringent regulatory norms to generics markets in developed countries
- The competition for generics and bio-generics production is increasing with higher capacity and production costs
- The barriers to entry are higher in development of new drugs.

#### 7.4. Competitors to India

**Bangladesh:** Bangladesh has achieved tremendous success in Pharmaceutical sector in the last few years. Pharmaceutical industry is using state-of-the-art manufacturing technology and highly skilled human resources. This industry is the fastest growing sector in Bangladesh. The domestic market size is US \$ 1.136 billion (€ .91 billion) with a growth rate of 23.59 % in 2011. Within next 4-5 years, the expected market size of Bangladesh would be around US \$ 2.5 billion (€ 2.01 billion) per year.

**China:** Total foreign trade involving pharmaceuticals rose 10.27 % to US \$ 89.69 billion (€ 71.15 billion) in 2013, with exports up 6.84 % and imports rising 15.17 % compared with 2012, according to figures from the China Chamber of Commerce for Imports & Exports of Medicine & Health Products. However China's pharmaceutical industry is entering a critical period of transformation as it is losing its traditional competitiveness, such as price and is also faced with sluggish international market.

**Singapore:** A surge in pharmaceutical production has helped Singapore's increase in manufacturing output. Overall, general output grew by 12.4 % in July 2014 compared to the same period a year ago. However, drug manufacturing levels were 125.4 % higher than 12 months previously.

#### 8. Market entry strategies and requirements for Indian companies

To maximize the chances of success in Germany, we recommend the following:

- **Investment in the Indian Pharmaceutical industry by German companies and vice versa to create mutual opportunities in both geographies:** 100% Foreign Direct Investment (FDI) is allowed under automatic route in the drugs and pharmaceuticals sector, including those involving use of recombinant technology. Besides, FDI up to 100% is permitted for brown field investments (i.e. investments in existing companies), in the pharmaceuticals sector, under the Government approval route. Companies in India should look for probable investors from Germany.

While pharmaceutical MNCs already present in India are further consolidating their presence through acquisitions, many MNCs have staged a re-entry after

2005. The share of pharmaceutical MNCs in the domestic pharmaceutical market is estimated to increase to 35 % by 2015 and this could be a very effective way of Indian companies tying up with German companies to help them access the Indian market in lieu of accessing the German market.

- **Cost Efficiency:** India rates higher than other countries on cost efficiency. This is visibly reflected in the manufacturing costs of US FDA-approved plants in India, wherein the costs are 65 % lower than that in the US and 50 % lower than that in Europe. There are significant sub contracting opportunities for Indian pharma companies using this argument to large German companies who are under cost pressure as well as short of qualified people. Many European companies like Sanofi, Boehringer Ingelheim, etc already outsource parts of their work chain to Indian companies.
- **Medical & Pharmaceutical Trade Shows:** Attending such Fairs is an economical way to meet prospective business partners, investors through the help of local consultants who know the industry and its regulations. It is also an apt opportunity to showcase Pharmaceutical products relevant for Germany (see Annexure).
- **Rigorous product selection:** Indian companies should accelerate the incorporation of commercial requirements in the development process and raise the bar on commercial gating factors. They should eliminate programs that do not meet the requirements. Often foreign companies do not evaluate the German market well enough and make mistakes in forecasting product demand and timing.
- **Commercially relevant evidence:** Indian companies should engage authorities early with scientific, patient-relevant outcomes, and economic evidence in order to leverage the quality metrics. This will give an edge over other players/ countries trying to do business in Germany as many foreign players make the mistake of engaging the authorities too late in the process.
- **Outsourcing:** Spiraling costs, expiring patents, low R&D cost and market dynamics are driving the MNCs to outsource both manufacturing and research activities. India with its apt chemistry skills and low cost advantages, both in

research and manufacturing coupled with skilled manpower will attract a lot of business in the days to come.

The rules are changing and value capture is becoming increasingly difficult. However, adapting to the evolving commercial requirements and succeeding in Germany still offers a critical geographic component not easy to replace elsewhere.

The Indian Pharma industry accounts for 6% of the global Pharma industry in value and 25% in volume. One in every three children around the world is immunized by vaccines made in India. The government has created a special entity in partnership with private firms for a 'Brand India Pharma' campaign aimed at refurbishing drug exporters' image. At US \$ 14.84 billion (₹ 90,000 Crore; € 11.94 billion), the growth rate of India's Pharmaceutical exports slowed sharply in 2013-14 to just 1.2%. The near stagnation in growth is because of import alerts and bans by US regulators, a slowdown in the European Union and increased competition.

Recently, Pharmaceutical giants like Ranbaxy, Wockhardt, Sun Pharma and some others have come under the USFDA scanner. A few of their products have been banned or recalled and some of their processes red-flagged for non-compliance with current Good Manufacturing Practices (cGMPs).

The absence of global harmonisation of quality systems makes it all the more challenging for India that exports to the US, Europe, Australia, Japan, etc, to comply with a plethora of global regulatory guidelines across diverse geographies and may sometimes fall short of regulatory expectations. These deviations are taken as non-compliance even though it may not impact the safety and efficacy of the drug.

These issues of quality control (mostly minor) are damaging India's reputation. While a few Indian drug makers are to blame for this, it is evident that vested interests among global pharma stakeholders are resorting to propaganda to project the whole of India's pharma industry as having poor regulatory standards and hence the good manufacturing and quality processes of many Indian companies have come under a shadow.

In order to live up to the challenges of increasing market share in existing and new markets and countering the negative publicity in some countries by vested interests, Ministry of Commerce & Industry, Government of India has advised Pharmexcil

(Pharmaceuticals Export Promotion Council of India) to launch a Brand India Pharma campaign globally. Brand India Pharma campaign is being held in partnership with India Brand Equity Foundation.

## 9. ValueWerk's Analysis and Suggestions

Our outlook on the Indian Pharmaceutical Industry's prospects in Germany remains favorable, benefitting from healthy growth in the domestic formulations business and steady growth expected in the generics space after patent expiries. While companies may face pressure on profitability, volume growth would continue as healthcare reforms initiated by government may push growth in generics. India is also donning the role of 'hidden vaccine heroes' and driving down the cost to about \$ 1 (€ 0.81) per dose in the global fight to protect kids from deadly diseases. Relatively lesser known pharmaceutical companies like Serum Institute of India, Bharat Biotech, and Biological E, have become some of the most valuable partners in global health. Key challenges facing the industry are potential implementation of the new pricing policy in India, increasing competitive pressure in the chronic segments, aggressive approach such as authorized generics by innovators in the US and healthcare reforms in German and European markets.

### Our suggestions with regard to Germany are:

- **Increase investments in R&D:** There is great need of innovation in IPI. Companies need to spend money on R&D, not only for growth of market but also to strengthen their positions. Incremental innovation can be a good starting point. Companies can then move towards pure R&D. IPI is still waiting for its first indigenous new product launch.
- **Boost spending on brand building:** Indian companies will have to increase and optimize spending on brand building. In case a company is successful in establishing its brand, it will be easy to create a market for its brand generics not only yield better margins but also provide an edge over competitors. One positive is that the government is concerned about domestic pharma companies. Recently, the Department of Industrial Policy and Promotion (DIPP) raised concerns over allowing 100 % FDI in the pharma sector. Although the Cabinet has rejected the proposal to reduce FDI, it has agreed to one condition - non inclusion of the non-compete clause in all brown field pharma transactions. This

will help Indian players - even if they sell their businesses to MNCs, they can restart or invest in new ventures of a similar nature.

- **Follow good manufacturing practices and SOPs (Standard Operating Procedures):** No doubt foreign markets are opening up for generics and Indian companies are taking due advantage of the situation. But we have to be more cautious about the quality of products manufactured in the country. After Ranbaxy, Wockhardt also has been into troubles with US Food and Drugs Administration. If things continue in the same vein, the whole domestic pharma industry may suffer. Domestic companies should follow all the SOP guidelines and be responsible about quality which will surely benefit them in future.
- **Shift towards high value generics:** Indian companies will have to shift their business models which are based on low value generics, to high value generics which are difficult to copy and to niche or specialty products or bio-similars. Biocon's launch of Herceptin bio-similar (CANMAb) is the latest example in this category. Dr. Reddy's and Sun Pharma have high profit margins due to their focus on specialty products.

#### **Why should Indian Pharma look at Germany?**

- **Economic Profile:** The latest studies show that Germany is the number one location for investors in Europe. Both economic stability and the size of the market are key factors that ensure business success here. Companies also benefit from Germany's excellent global economic links and the international exchange of knowledge, products and specialists.
- **Foreign Direct Investment:** Every year more and more companies discover Germany as a secure and rewarding investment location. In the last ten years, Germany's FDI stocks have doubled to reach an amount of almost € 600 billion in 2013. Around 55,000 foreign companies are already operating in Germany, employing almost three million people.
- **R&D Framework:** German firms are global leaders in the development of new technologies. For over a century, the "Made in Germany" label has stood for

innovation and excellent quality. This makes Germany the top exporter in Europe and the second largest in the world.

- **Business Climate:** Germany is one of the most attractive business locations in the world. The German legal system protects property and individual rights. Competitive tax regulations and a wide range of funding options offer a strong framework for investment. The excellent infrastructure and highly qualified workforce are further factors that contribute to sustainable business success.
- **Availability of Incentives:** Germany offers different financial support measures for investment projects tailored to different requirements of the individual project development steps. Measures include supporting direct investment costs, labor-related expenses, and direct research and development project costs. The following financial incentives are available from the German government:-
  - **Grants for Investments:** Production site set-up or service location development is supported by investment incentives programs providing support in the form of cash grants. The most important grant program for investments is the “Joint Task Improving Regional Economic Structures” (Gemeinschaftsaufgabe “Verbesserung der regionalen Wirtschaftsstruktur” GRW). The maximum level of support that is permitted varies within the country. At its simplest, this is dependent upon a region’s level of economic development. In the maximum support-areas in Germany, large companies can receive up to 20 % of their eligible investment costs reimbursed; medium sized companies up to 30 % eligible costs reimbursed, and small companies up to 40 % eligible costs reimbursed. The maximum support areas are located in eastern Germany.
  - **Grants for Research and Development:** R&D incentives programs in Germany focus on non -repayable grants. These generally provide money for R&D project personnel expenditure. Other costs for instruments and equipment may also be eligible if they can be clearly assigned to the relevant R&D project.

- **Projects Grants for Hiring Personnel:** Germany's Federal Employment Agency (Bundesagentur für Arbeit) and the German federal states offer a range of labor-related incentives programs designed to fit the different company needs when building workforce. They are divided into Recruitment support/ Pre-hiring training/ Wage subsidies/ On-the-job-training etc.
- **Public Loans:** Public loans occupy an important position in the German funding system and are available at federal (KfW Bankengruppe), state (state development banks) and EU (European Investment Bank) levels. Long credit periods, attractive interest rates and repayment free periods are the most important features of this funding instrument. Small and medium -sized enterprises in particular are often entitled to preferential conditions. Public loans are available for the full range of funding purposes.
- **Public Guarantees:** New companies often experience difficulties securing financing as the required loans often cannot be collateralized to a sufficient degree. In these cases (with economically appropriate projects), so-called "public guarantees", can replace or supplement any shortfall in loan securities. This instrument delivers additional confidence in favor of the main bank concerning the financed investment project in Germany. Selection of the most adequate guarantee program depends also on the size of the enterprise and the investment region. In general, up to 80 % of the total value of the concerning loan amount is insured.

We strongly believe that often Indian pharma companies lose out on excellent German business opportunities simply because they are not on the top of the mind of local businesses to be invited for participation and hence missing out on the "pull" factor wherein they are proactively approached to do business in Germany (which happens positively in the IT and automotive sector). At the moment Indian pharma companies rely more on the "push" factor where they come to Germany for expansion needs but the best opportunities are already grabbed by other more proactive and better reputed international players whom the local German pharma industry approached with opportunities as and when they arose. This needs to be changed radically in future.

## 10. Annexure 1 – Handbook of addresses and important contacts in the industry

### **Verband Forschender Arzneimittelhersteller e.V.**

(German Association of Research-based Pharmaceutical Companies)

Hausvogteiplatz 13

10117 Berlin

Phone: +49 30 20604-0

Fax: +49 30 20604-222

E-Mail: [info@vfa.de](mailto:info@vfa.de)

Internet: [www.vfa.de](http://www.vfa.de)

### **Federal Association of the Pharmaceutical Industry**

Friedrichstraße 148

10117 Berlin

Tel .: +49 (30) 27909-0

Fax: +49 (30) 27909-361

E-Mail: [info@bpi.de](mailto:info@bpi.de)

Internet: [www.bpi.de](http://www.bpi.de)

### **ABDA - Federal Union of German Associations of Pharmacists**

Jägerstr. 49/50

10117 Berlin

Tel: 030 / 40004-0

Fax: 030 / 40004-598

E-Mail: [abda@abda.de](mailto:abda@abda.de)

Internet: [www.abda.de](http://www.abda.de)

### **Expopharm**

Carl-Mannich-Straße 26

65760 Eschborn

Phone +49 6196 - 928 402

Telefax: +49 6196-928404

Internet: [www.expopharm.de](http://www.expopharm.de)

### **MEDICA**

Messe Düsseldorf GmbH

Postfach 10 10 06, 40001 Dusseldorf

Phone: +49 (0) 211 4560-01

Fax: +49 (0) 211 4560-668

Email: [info@messe-duesseldorf.de](mailto:info@messe-duesseldorf.de)

Internet: <http://www.messe-duesseldorf.de/>

## 11. Annexure 2 - Important Pharma and other Fairs in 2015

### Pharma Fairs

Esoteric fairs Mannheim 23-25 Jan 2015 Mannheim, Germany	Medizin Expo 30 Jan-01 Feb 2015 Stuttgart, Germany
Vision Pharma Modern Processes - Innovations and Solutions 19 May-21 May 2015 Stuttgart, Baden-Wurttemberg Germany	Expopharm International Pharmaceutical fair Audience: professional visitors only 30 Sept -03 Oct 2015 Düsseldorf, North Rhine-Westphalia Germany

### Other Fairs of interest

Impuls 09-10 Jan 2015 Cottbus, Germany	Partner Pferd 15-18 Jan 2015 Leipzig, Germany
Glasses & Co 17-18 Jan 2015 Dortmund, Germany	Omnocard 20-22 Jan 2015 Berlin, Germany
Esoteric fairs Mannheim 23-25 Jan 2015 Mannheim, Germany	Yoga Expo 23-25 Jan 2015 Munich, Germany
Energetika Boblingen 23-25 Jan 2015 Boblingen, Germany	World Of Yoga Munich 23-25 Jan 2015 Munich, Germany
Spirit and Life Dortmund 24-25 Jan 2015 Dortmund, Germany	BRILLE & CO DORTMUND 24-25 Jan 2015 Dortmund, Germany
Therapro 30 Jan-01 Feb 2015 Stuttgart, Germany	Medizin Expo 30 Jan-01 Feb 2015 Stuttgart, Germany
Healthy and Active 31 Jan-01 Feb 2015 Marburg, Germany	BIO terra-Fair Gottingen 07-08 Feb 2015 Gottingen, Germany

German Spa Days 07-08 Feb 2015 Baden-Baden, Germany	Vita Well 07-08 Feb 2015 Goppingen, Germany
Health-Regional.de-The Fair 07-08 Feb 2015 Bayreuth, Germany	Healthy & Active 07-08 Feb 2015 Ludwigsburg, Germany
Abf Active & Fit 11-15 Feb 2015 Hannover, Germany	Aktiv & Fit Hanover 11-15 Feb 2015 Hannover, Germany
Reisen Freizeit Caravan Boot 13-15 Feb 2015 Cottbus, Germany	Leipzig Insurance Fund And Exhibition 14-15 Feb 2015 Leipzig, Germany
Para Vital Fair Bremen 14-15 Feb 2015 Bremen, Germany	Job Medi 20-21 Feb 2015 Bochum, Germany
Energetika Aalen 20-22 Feb 2015 Aalen, Germany	Inviva 20-21 Feb 2015 Nuremberg, Germany
Wellness & Gesundheits Messe 21-22 Feb 2015 Lahr, Germany	My Life Allgau 21-22 Feb 2015 Kempten, Germany
Didacta Die Bildungsmesse Stuttgart 24-28 Feb 2015 Stuttgart, Germany	Vitality Mass Lubeck 27 Feb-01 Mar 2015 Luebbeck, Germany
VeggieWorld Wiesbaden 27 Feb-01 Mar 2015 Wiesbaden, Germany	BIO terra-Fair Villingen 28 Feb-01 Mar 2015 Villingen-Schwenningen, Germany
Natural Life Cologne 28 Feb-01 Mar 2015 Cologne, Germany	Health 28 Feb-08 Mar 2015 Erfurt, Germany
Harmonie Leipzig 28 Feb-01 Mar 2015 Leipzig, Germany	Health Siegen 28 Feb-01 Mar 2015 Siegen, Germany

Wohlfühlmesse Gelsenkirchen 01 Mar 2015 Gelsenkirchen, Germany	Hanse Show Wismar 05-08 Mar 2015 Wismar, Germany
Diabetes Fair 06-08 Mar 2015 Munster, Germany	Active Vital 06-08 Mar 2015 Dresden, Germany
Health Fair Franc Active & Vital 06-08 Mar 2015 Bamberg, Germany	Horizon Munster 07-08 Mar 2015 Munster, Germany
Moers Health Fair 07-07 Mar 2015 Moers, Germany	Thuringian Health Fair 07-08 Mar 2015 Erfurt, Germany
International Dental Show 10-14 Mar 2015 Cologne, Germany	Spirit and Life Duisburg 14-15 Mar 2015 Duisburg, Germany
INTERBIOLOGICA 2015 14-15 Mar 2015 Wiesbaden, Germany	Health & Vitality Hanover 16-20 Mar 2015 Hannover, Germany
Therapie Leipzig 19-21 Mar 2015 Leipzig, Germany	Esoteric Fairs Cologne 20-22 Mar 2015 Cologne, Germany
Stade Aktuell Exhibition 20-22 Mar 2015 Stade, Germany	Health As A Profession 20-21 Mar 2015 Berlin, Germany
Bella Vita 21-21 Mar 2015 Chemnitz, Germany	Koblenz Healthy 22-22 Mar 2015 Koblenz, Germany
ALTENPFLEGE + PROPFLEGE HANNOVER 23-25 Mar 2015 Hannover, Germany	Berlin Vital Fall 26-28 Mar 2015 Berlin, Germany
Health And Vitality In Real Life 50 27-29 Mar 2015 Schwerin, Germany	Balance 28-29 Mar 2015 Offenburg, Germany

Heldenmarkt Ruhr 28-29 Mar 2015 Bochum, Germany	Fibo Power 09-12 Apr 2015 Cologne, Germany
Yoga Expo Stuttgart 09-12 Apr 2015 Stuttgart, Germany	Vintagrande 11-11 Apr 2015 Dresden, Germany
Fibo 09-12 Apr 2015 Cologne, Germany	International Saarmesse 11-19 Apr 2015 Saarbrücken, Germany
Connecting Healthcare IT 14-16 Apr 2015 Berlin, Germany	Energetika Denkendorf 17-19 Apr 2015 Stuttgart, Germany
CAM 2009 18-18 Apr 2015 Düsseldorf, Germany	BarnimBau Eberswalde 18-19 Apr 2015 Eberswalde, Germany
Gesund & Vital 18-19 Apr 2015 Waiblingen, Germany	Medtec Europe 21-23 Apr 2015 Stuttgart, Germany
Natural Life Cologne Bergisch Gladbach 25-26 Apr 2015 Bergisch Gladbach, Germany	Personal Hamburg 06-07 May 2015 Hamburg, Germany
RETTmobil Exhibition 06-08 May 2015 Fulda, Germany	Bremer Care Congress & Exhibition 06-08 May 2015 Bremen, Germany
German Wound Congress & Exhibition 06-08 May 2015 Bremen, Germany	Life And Death 08-09 May 2015 Bremen, Germany
Para Vital Fair Dusseldorf 09-10 May 2015 Düsseldorf, Germany	Personal Expo 19-20 May 2015 Stuttgart, Germany
Corporate Health Convention 19-20 May 2015 Stuttgart, Germany	Vision Pharma 19-21 May 2015 Stuttgart, Germany
Sight City 20-22 May 2015 Frankfurt, Germany	Rapid.Tech 10-11 Jun 2015 Erfurt, Germany

Esoteric fairs Frankfurt am Main 13-14 Jun 2015 Frankfurt, Germany	Energetika Buhl 19-21 Jun 2015 Buhl, Germany
Para Vital Fair Bielefeld 20-21 Jun 2015 Bielefeld, Germany	Sudhessen Messe 2015 17-26 Jul 2015 Erbach, Germany
Bio terra-Fair Konstanz 01-02 Aug 2015 Konstanz, Germany	Ophthalmic optics 15-16 Aug 2015 Dortmund, Germany
HandiCap - Die Messe 28-28 Aug 2015 Bergheim, Germany	My Market 30-30 Aug 2015 Essen, Germany
Esoteric fairs Ratingen 04-06 Sep 2015 Ratingen, Germany	Fachdental Leipzig 11-12 Sep 2015 Leipzig, Germany
Zukunft Personal 15-17 Sep 2015 Cologne, Germany	

**12. Annexure 3 - List of Biotechnology, Pharmaceutical and Life Sciences Companies in Germany by Category and Location**

<b>Company</b>	<b>Location</b>	<b>Business Type</b>
Aix Scientifics	Aachen	Contract Research
Phyton Biotech	Ahrensburg	Plant Cell Culture
Fresenius Kabi	Bad Homburg	Infusion Therapy
m2p-labs	Baesweiler	Bioprocessing Instruments
Bayer	Bergkamen	Small Molecules
3B Pharmaceuticals	Berlin	Peptides
Aaren Scientific	Berlin	Ophthalmic Devices
Bavarian Nordic	Berlin	Vaccines
Bayer	Berlin	Small Molecules
Berlin-Chemie (Menarini)	Berlin	Small Molecules
Biotronik	Berlin	Pacemakers, implantable defibrillators, stents and remote patient management.
caprotec bioanalytics	Berlin	Protein Isolation
CPL Sachse	Berlin	API Chemistry & Development
Haupt Pharma	Berlin	Small Molecules
Ibt Bebig	Berlin	Cancer Treatments
Injex Pharma	Berlin	Insulin Delivery
JPT Peptide Technologies	Berlin	Peptide Products
JPT Peptides Technologies (BioNTech)	Berlin	Peptide products and services
Noxxon Pharma	Berlin	L-aptamers
Penumbra	Berlin	Vascular/Surgical Devices
ProBioGen	Berlin	Contract Cell-Line Work
Roche	Berlin	Diagnostics
Silence Therapeutics	Berlin	RNAi
PlasmidFactory	Bielefeld	Plasmid Production
TeutoCell	Bielefeld	Cell Culture Media
Bayer	Bitterfeld	Small Molecules
Sirtex Medical	Bonn	Cancer Treatments
Haupt Pharma	Brackenheim	Packaging
Axiogenesis	Cologne	Stem Cell Products
Cato Research	Cologne	Full Service Contract Research
Cevec Pharmaceuticals	Cologne	Cell Line Expression Systems
Lonza	Cologne	Small Molecules, Biologics
Taconic Farms	Cologne	Laboratory Animals
UBC (Express Scripts)	Cologne	BioPharmaceutical Consulting & Services
TAD Pharma	Cuxhaven	Generic Small Molecules
Vibalogics	Cuxhaven	Contract Vaccines
Merck KGaA	Darmstadt	Small Molecules, Purification Equipment, etc.
IDT Biologika	Dessau-Rosslaud	Contract Research, Development & Manufacturing (Biologics, Liquid Small Molecules)
Affectis Pharmaceuticals	Dortmund	neurodegenerative and neuroinflammatory diseases
Protagen	Dortmund	Protein Research

Scienion	Dortmund	Microarray System
Cenix Biosciences	Dresden	RNAi-Based Screening
Menarini	Dresden	Small Molecules
AbD Serotec (Morphosys)	Dusseldorf	Biologics
MicroVention (Terumo)	Düsseldorf	Neuroendovascular therapeutic devices
Accovion	Eschborn	Contract Research
West Pharma	Eschweiler	Pharmaceutical Supplier
Evonik Industries	Essen	Small Molecules
Aeterna Zentaris	Frankfurt	Small Molecules
Cato Research	Frankfurt	Full Service Contract Research
eBioscience (Affymetrix)	Frankfurt	Cell Analysis Products
Ecron Acunova	Frankfurt	Clinical Research
Sanofi	Frankfurt	Small Molecules
TopoTarget	Frankfurt	Small Molecules, Biologics
Immunodiagnostic Systems	Frankfurt am Main	Immunoassay System
CellGenix	Freiburg	Cell Culture Products & Reagents
ChemCon	Freiburg	Contract chemical R&D; small molecule contract manufacturing
Pfizer	Freiburg	
Pieris	Freising-Weihenstephan	Modified Anticalins
Activaero	Gauting	Aerosolized Drug Delivery
Activaero	Gemuenden	Aerosolized Drug Delivery
Santen	Germering	Regulatory & Scientific Marketing
Miltenyi Biotech	Gladbach	Magnetic Cell Sorting Products
NextPharma	Göttingen	Contract Research & Development
Bayer	Grenzach	Biotech/Pharma/Chemical Giant
Roche	Grenzach,	Small Molecules
BioStorage Technologies	Griesheim	Sample Storage, Banking
Baxter	Halle	Medication Delivery
Probiodrug	Halle	Small Molecules
Scil Proteins	Halle	Ubiquitin-Derived Therapies
Cell Culture Service	Hamburg	Cell-based assays and reagents
IPM Biotech	Hamburg	Bioanalytical Services, Tools and Methods
AngioDynamics	Hamburg-Volksdorf	Array of Medical Devices
Affimed	Heidelberg	Antibody Therapeutics
Biomeva Manufacturing	Heidelberg	Contract Manufacturing & Analytical
Cytonet	Heidelberg	Cellular Therapies
Glycotope Biotechnology	Heidelberg	Biologics, Contract Manufacturing, Research, Services
Graffinity Pharmaceuticals	Heidelberg	Small Molecule Discovery
Lipid Therapeutics	Heidelberg	Inflammatory Digestive Treatments
Medicyte	Heidelberg	Cells for Research
PromoCell	Heidelberg	Cellular Products
Acris Antibodies	Herford	Antibodies, Kits, etc
Curetis	Holzgerlingen	Molecular Diagnostics
Pfizer	Illertissen	

CyBio	Jena	Automated Liquid Handling
InflaRx	Jena	Antibodies for Inflammation
Wacker	Jena	Small Molecules
Celonic	Julich	Analytical Contract Work
Dasgip	Julich	Parallel Bioreactor Systems
Pfizer	Karlsruhe	
Bayer	Kiel	Biotech/Pharma/Chemical Giant
Ferring Pharmaceuticals	Kiel	Manufacturing
Proteo Biotech	Kiel	Biologics
Axolabs	Kulmbach	Contract Oligonucleotide Work
Roche	Kulmbach	Small Molecules
Rentschler Biotechnologie	Laupheim	Biologics CMO
Bayer	Leverkusen	Biotech/Pharma/Chemical Giant
Santhera Pharmaceuticals	Lörrach	Orphan Neuromuscular Disease Targets
AbbVie	Ludwigshafen am Rhein	Small Molecules
EFK Diagnostics	Magdeburg	Diagnostics
HUMAN Diagnostics	Magdeburg	Lab Diagnostic Products
Orgentec Diagnostics	Mainz	in-vitro diagnostics
A2M Pharma	Mannheim	Small Molecules
Archimedes Pharma	Mannheim	Specialty Pharmaceuticals
Horizon Pharmaceuticals	Mannheim	Synthetic Hormones
MedGenesis Therapeutix	Mannheim	Neurologic Treatment - 'Convection Enhanced Delivery'
Roche	Mannheim	Diagnostics
Coriolis Pharma	Martinsried	Biologics Contracting
Evotec	Martinsried	Target Identification
Exosome Diagnostics	Martinsried	biofluid-based molecular diagnostic tests
Oncolead	Martinsried	Cellular Screening for Cancer Diagnosis
ProJect Pharmaceuticals	Martinsried	Protein Formulation & Process Development
Curacyte	Munich	Modified Hemoglobin
Daiichi Sankyo	Munich	Small Molecules
Isarna Therapeutics	Munich	Synthetic Nucleotides
Priaxon	Munich	Small Molecule Discovery & Development
Trion Pharma	Munich	Trifunctional Antibody
Wacker	Munich	Small Molecules
Haupt Pharma	Münster	Small Molecules
Thermo Fisher	Nidderau	Lab Supplies and Equipment
Roche	Penzberg	Diagnostics
4SC	Planegg	Autoimmune & Cancer Small Molecules
Agennix	Planegg	Small Molecules
Bavarian Nordic	Planegg	Vaccines
Biomax Informatics	Planegg	Genome Analysis, services
CRELUX	Planegg	Drug Discovery Services
Emergent BioSolutions	Planegg	Biologic Vaccines
MorphoSys	Planegg	Biologics

Proteros Biostructures	Planegg	Chemical Structural Analysis
Sirion Biotechnology	Planegg	Gene Expression
Supremol	Planegg	Fc Technology
U3 Pharma (Daiichi Sankyo)	Planegg	Biologics
4SC-Discovery (4SC)	Planegg- Martinsried	Drug Discovery Services
ChromoTek	Planegg- Martinsried	Research Antibodies & Reagents
Corden Pharma	Plankstadt	Contract Small Molecules
Biotie Therapies	Radebeul	Small Molecules, Biologics
Abbott	Rangendingen	Stents
NeuroTherm (St. Jude Medical)	Ratingen	Surgical and Medical Devices
Vetter	Ravensburg	Aseptic Filling
Amgen	Regensburg	Biologics
Haupt Pharma	Regensburg	Small Molecules
AllergoPharma (Merck KgaA)	Reinbek	Specific Immunotherapy Allergy Treatment
Cellendes	Reutlingen	3D Cell Culture
Sekisui	Rüsselsheim	Diagnostics
Toxikon	Sankt Ingbert	Medical Devices, Drug Delivery
Catalent	Schorndorf	Dosage Form Development
OctaPharma	Springe	Biologics
SAFC (Sigma-Aldrich)	Steinheim	Small Molecule Intermediates
Theragenesis	Stutensee	Contract Development
CureVac	Tübingen	mRNA treatments
CTI Clinical Trials	Ulm	Clinical Trials & Consulting
Ratiopharm (Teva)	Ulm	Generic Small Molecules
Recipharm	Wasserburg	Sterile Manufacturing
Klocke Group	Weingarten	Contract Manufacturing
Cytonet	Weinheim	Cellular Therapies
AbbVie	Wiesbaden	Small Molecules, Biologics, Devices, Diagnostics
HUMAN Diagnostics	Wiesbaden	Lab Diagnostic Products
InspireMD	Winsen	Medical Devices
Biobase	Wolfenbüttel	Biological Databases
Haupt Pharma	Wolfratshausen	Small Molecules
Haupt Pharma	Wülfing	Small Molecules
AiCuris	Wuppertal	Anti-Infectives
Bayer	Wuppertal	Small Molecules
Spectranetics	Würzburg	Single-use cardiovascular medical devices

### 13. About ValueWerk

**ValueWerk** specializes in facilitating Indian & German companies do business with each other. It has consulted companies from diverse industries involving M&A and JV negotiations, Business Development, Marketing & Branding services, Strategic Investments, and the setup of European family offices for Asian investors. For queries, please contact:

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