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## EICC Roundtable sets in motion EU-India cooperation in pharmaceutical industries

The two days deliberations of the Europe India Chamber of Commerce - Indian Merchants' Chamber (EICC-IMC) Roundtable on Pharmaceutical industry held in Brussels on 21-22nd September 2008 which brought together major pharma companies of Europe and India; representative of pharmaceutical organizations in India and Europe including officials of the government of India and the European Commission extensively debated specific issues and factors that hinders market access opportunities of the pharmaceutical and pharma related products of Indian drug manufactures into Europe and vice-versa. In addition to discussing collaboration in trade and investment in this sector and understanding of the current regulatory framework in place both in the European Union and India, the participants recognized the need for closer cooperation on exchanging information and experience on development in research and innovation and joint venture on products of generics. The European drug companies were represented by high level delegation from the German Pharmaceutical Industry Association (BPI), and the Indian side by pharmexcil and the Indian Pharmaceuticals Alliance respectively. The Roundtable was organized in association of the Embassy of India in Brussels.

The Roundtable held in the Hotel Sheraton and in the European Parliament presented a unique opportunity for Indian and European drug manufacturers to focus on rising potential for Pharmaceutical sector investment in India and provided them an opportunity to discuss outstanding issues including implementation strategies on compliance of Intellectual Property Rights and GMP. The Roundtable assumed importance in the wake of unprecedented overseas acquisitions by Indian Pharmaceutical companies' particularly in Europe and served an important step towards creating a suitable and sustainable framework for future cooperation between European and Indian drug manufacturers.

The Roundtable drew more than one hundred academicians, researchers, professionals, policy makers and industry leaders from Europe and India who termed the event as upbeat, highly useful and informative. The Roundtable participants and speakers identified a number of challenges that India and Europe face in the changing dynamics of the pharma sector. The following are some of the important observations made during the two day session:

Pharma sector is the key to India's expanding trade and economic ties with the European Union. The EU has opened up opportunities for greater economic activities in this area, mainly because of the inherent strength of the Indian industry in biotech and pharmaceuticals sectors. Although known as a major supplier of generic drugs, India has begun to forge new alliances with big US and European pharma companies. Such collaborations are helping it shepherd into a new era of innovative drug discovery, but regulations governing patents, drug approvals, and clinical trials appeared still in the process of being updated.

With respect to operational capabilities, the participants observed that although Indian pharma manufacturers on average have made greater inroads in key areas, such as quality management, there are a number of key areas such as lack of investment in R&D prevents many Indian drug manufacturers from taking a lead in the global competition; lack of financial capacity to build the production and distribution capabilities needed to sustain double-digit annual growth rates; lack of scale in crucial areas of production, distribution, and marketing/sales - key capabilities needed to efficiently access nation-wide and global markets and lack of capabilities and investment in technology and infrastructure to support rapidly growing domestic and international business are needed to be addressed.

On the issue of intellectual property rights and regulatory framework in India which took the centre stage of discussion, it was observed that the introduction of new patent laws and drug regulations in India, the transition of local Indian drug companies to global partners with big pharma have been relatively smooth so far. However, the impact of these changes on the ability of Indian companies to retain their philosophy

of supplying cheap drugs to the developing world and the effects of these changes on clinical trials conducted in India remain to be seen. India has entered a new era with accession to TRIPS-compliant patent regime and many foreign companies are looking for opportunities in low volume high value product launches, excellent chemical and process engineering skills to move India towards international standard GMP compliance.

In addition to changes to Indian patent law, India has brought several changes in its National Pharmaceutical Policy, which grants data protection to drug companies for valuable data collected during clinical research. Such sweeping regulatory improvements are enhancing global confidence in the drug research environment in India. However, it was pointed out that despite Indian government's decision to bring its laws into conformity with the World Trade Organization, concerns persist among global drug makers in general over the lack of IP protection, lax restrictions on parallel trade and regulatory uncertainty, and as such doubts linger over whether the laws are being effectively enforced.

On the issue of compliance of IPR and quality standards, the Indian side refuted the contention that the Indian companies lack seriousness on the compliance, and said that the fact that 60 production locations have been certified by the WHO which implies that they comply with strict quality standard imposed by the FDA of US, prove that it has an effective compliance mechanism in place. It was therefore felt that there was a lack of awareness and information including elements of inbuilt attitudinal reservation in Europe about the developments in the regulatory environment in India, which can be, according to them, one of the most pioneering examples of observance and compliance. It was observed that Western pharma companies are using the legal system and are litigating aggressively to prolong their intellectual property rights even after the expiry of patents. And since, Indian generic companies can not enter the field of new drug discoveries, over the next few years these companies will be reduced to contract manufacturing for big multinationals.

Representatives from India observed that the whole idea of authorizing a generic drug maker is to block the Indian companies from aggressively entering into European market. Authorized generics market still represents a relatively small part of the overall generics industry, and it is unclear if Indian companies have any special advantage there.

Indian side expressed concern over the creation of "artificial non-tariff technical barriers" in the trade of traditional medicine products in the name of safety and pointed out that this infringes on the rights of people in developed countries to have products of their choice They also voiced concern of the European Union directive on traditional herbal medicinal products. It was pointed out that these regulations mean that manufacturers have to apply for a license for every herbal product, and each must comply with official standards. The directive also demands that a traditional herbal medicinal product must be shown to have been in use for 30 years in the EU (or at least 15 years in the EU for it to be licensed and obtainable over the counter. Referring to the issues pertaining to market authorization of traditional medicine products and non-tariff trade barriers to the trade of national health products, they pointed out that these are having an adverse impact on trade and that to shut out traditional medicine products on arbitrary technical barriers in the name of safety would be against the interest of patients and consumers. It was informed that Poly-herbal products originating from non-European traditional medicinal cultures, such as Ayurveda are facing rough ride in the EU, falling between the two stools of European law designed for traditional herbal medicines and food supplements respectively. In that context it was mentioned that that in order to streamlining this segment, suitable design to generate proofs through clinical trials and other quality control measures was suggested

On the issue of trade and investment opportunities in the pharma sector in the context of changing dynamics of global Pharma industry with particular interest in India and Europe, it was observed that big opportunities lie for enhancing cooperation. It was observed that the involvement of global pharma companies as partners will speed the emergence of big Indian pharma companies in global markets. As a market, India holds appeal to global pharma companies, particularly as they confront slowing growth and pricing constraints in maturing markets of developed countries.

India presents major opportunities for multinational pharmaceutical companies in clinical trials, contract research and manufacturing. The licensing opportunities for big pharmaceutical companies as well as the collaborative business model including services give access to low cost smart intelligent base, indigenous technology and most importantly the large domestic market.

To reach India's vast market, global players are creating partnerships to provide affordable medicines, in some cases acquiring older products that are off patent. For Indian companies, focus has been the key to growth, but with pressure growing in commodity generics markets, the Indian pharma firms need to pay close attention to operating efficiency and cost structure to penetrate on vital markets in America and Europe.

Almost $80 billion worth of drugs will lose their patents in the next five years, and India has a significant opportunity to get a share of that pie. Indian companies will have to get creative if they want to move away from the generic business. Biogenerics - generic versions of biological products - could be an attractive market. It requires heavy investment and entirely new capabilities in manufacturing, regulatory expertise and distribution. Indian companies are seriously looking at outward investment opportunities, typically acquisitions or a controlling stake with a view to gain market access to US or EU markets, by leveraging on the regulatory compliances & distribution networks of the acquisitions.

Since India lacks in the capacity for drug development, they have, therefore, chosen to work with pharmaceutical multinationals. By following this strategy for product development, the companies are destined to invest mainly in research for diseases in which these multinationals too have interest.

Although Indian drug companies are doing reasonably well in the supply of generics to regulated markets of the developed world, they need to invest in R&D and technological up-gradation to succeed in competing with the existing competition in the markets for generics. Given the fact that their resource position is limited and they do need larger markets to obtain sufficient returns on R&D for new product development, there are opportunities for global drug companies to invest. It can help the drug development capacity to facilitate such policy reforms that would correct the disparities in R&D and benefit all stakeholders.

The Indian Biotechnology is developing with government initiatives and private sector participation with tremendous opportunities to be explored and paving ways to more fruitful partnerships with biotechnology companies and world class research institutes. Although the government has initiated several measures to ensure the quality of drugs available in India, urgent steps are required against substandard/counterfeit drugs which accounts for 15 per cent products in the market.

The healthcare industry in India is one of the fastest growing industries. The industry is worth US$34 billion and is growing at an impressive rate of 13%. The growth is driven by the growing health awareness among India's burgeoning middle class. It was observed that providing adequate health care is one of the biggest changes for India, and it will take India decades before it can catch up with the developed world. Although new health insurance initiatives in India have increased the affordability of the middle class population as there is a very small part of the population who can afford good quality healthcare expenditure. It was observed that due to India's vast rural population, only one third of the country's inhabitants have access to medical care. India's health care offers Investment opportunities for the pharma companies in the developed countries. Information technology and telecommunications have an increasingly enabling role to play in India's health care management.

On the issue of clinical trials, it was felt that there is a need to improve the regulatory approval process and increase public awareness and transparency. Major pharmaceutical companies have started clinical trials across India. What is required in India is strategic identification of market viability. The estimation of opportunities and forecasting the market is an important step towards assessing the commercial viability for drug development and clinical trials. Segmentation is important as for clinical trial opportunities, segmenting the clinical trial service providers will help in estimating the market.

Equally important, participants observed was the vulnerability of Indian patients enrolled in clinical trials as most of them lack state health insurance. Poor patients see clinical trials as a way to get temporary healthcare, but as there are no effective legislation or guidelines in India requiring drug companies to

provide the medication after the drug gets approved and sold in India, such patients can be left in the lurch. Unlike the West, patients in India in general are not insured therefore the Indian government needs to devise proper mechanism under which patients get insurance both during and after the trial.

With a lack of new blockbuster drugs in the pipeline, the global pharmaceutical industry is increasingly under financial pressure. Such financial pressures may explain in part why big pharma is rushing to set up collaborations with local companies in cost-effective locations like India. In addition to a significant pool of trained biomedical and chemistry professionals and a strong bioinformatics tradition, India has a large genetically diverse population from which to recruit patients for clinical trials. The new alliances between big pharma companies in Europe and Indian drug companies will go a long way in transforming India's role in drug discovery and may change the way multinationals partner with companies in other countries.

India is increasingly becoming an integral part of the global pharma value chain, as large global pharma companies continue to increase their sourcing of APIs, offshoring of clinical development and partnering with domestic companies for new product development and marketing in India. It was also observed that beyond the country's impact on innovation and manufacturing of the pharma sector, India will have a larger impact on global pharma's tax, regulatory and IT environment. Therefore collaborations with European companies will provide an opportunity to the Indian companies to tap into the world's global research networks and to gain access to new technologies while providing a platform for big global pharma companies to leverage the scientific talent available in India. Creation of a business and regulatory environment conducive for innovation and research will lead to significant investments in the country.

Liberation of trade and investment regime in India over the last decade has already made it one of the most favoured destinations for research and development location. India's status of being compliant with the international trade and patent conventions also takes care of one of the most sensitive issue of securing intellectual property rights in R&D. Therefore it was hoped that a significant outcome of this Roundtable would be to create better understanding between Indian and European pharma companies.

The participants were informed about opportunities for Indian pharma companies to participate in the EU's FP7 It was observed that although participation from India is encouraging but it was not significant, and as such Indian pharma companies have an opportunity to take full benefit of the EU's assisted research programme is this sector.

There was the general proposition that the Roundtable should be seen as the beginning of a continued deliberation, and not the end. The Roundtable asked the EICC to bring forward its linkages and international networking capabilities to ensure follow up activities of this initiative. It was also expressed that the deliberations have led to some concrete and feasible proposals of actions appropriate to the issues facing the global pharma industry in general and Indian and European pharma industry in particular, the EICC should take special interest in this sector.

India provides a unique platform for affordable drug development. There was a general view that since the Indian Pharmaceutical industry is already growing at a rapid pace to compete in the international market, Indian pharma Industry has to reach the highest level of quality standards as well as management systems. And to achieve this, what is important is better coordination and management practices?. Therefore to overcome the administrative and management obstacles and to meet new challenges to achieve highest level of quality & excellence, Pharma industries needs to seriously upgrade their know how to achieve the ultimate objective of profit growth and excellence.

The success of the Roundtable should be judged by the degree of enhanced cooperation between Indian and European pharma companies. Participants agreed that the pharma Roundtable should be able to provide a roadmap for the Indian pharmaceutical industry to realise its potential, become competitive through alliance and partnership and identify enablers and imperatives to attract good human capital to the pharmaceutical industry.

Although India has proved itself as an excellent value proposition for global pharma companies, most of whom are leveraging on India's cost competitiveness and large pool of technically skilled manpower including emerging as a preferred global supplier of high quality drugs and intermediates at very cost effective prices, there are still a few concerns in terms of strengthening the regulatory infrastructure and framework within the country, investing in developing educational infrastructure to ensure a continued adequate skilled talent pool supply, and building stronger capabilities on the discovery front. It was felt that India needs to implement strong patent legislation, data exclusivity, and improve IPR infrastructure and enforcement in order to achieve its potential as an R&D powerhouse.

There was unanimous view that there was a need for a suitable mechanism where cooperation (between European and Indian pharma companies) rather than wasteful rivalry-oriented competition should be encouraged. It was suggested that the next meeting should be held in New Delhi next year to strengthen the interaction for improved collaboration.

The inaugural session of the Conference was addressed by India's Ambassador to the Belgium and EU His Excellency Dr. Jaimini Bhagwati, EICC Chairman MEP Dr. Christian Ehler, EICC Co-Chairman Mr. Sanjay Dalmia, Deputy Director General of BPI Dr. Barbara Sickmüller, pharmexcil Additional Executive Director Mr. Raghuveer Kini and EICC Secretary General Mr. Sunil Prasad. In the business session in the European Parliament, those who spoke and made presentations were: EICC Patron Dr. Prem Sharma, Mr. Martin Terberger (European Commission), Mr. G S Sandhu and Mr. Shiv Basant, Joint Secretaries of the Government of India, Mr. Avinash Mandale (Bilcare), Dr. Norbert Gerbsch (BPI), Mr. Marek Ruzikowski (representing Polish Pharma industry), Mr. D G Shah (IPA), Dr. Thomas D Seuss (Jungblut & Seuss), Dr. Heinz Hammann (EFPIA), Dr. P M Murali (DCRD), Mr. Peter Verplancken (Flanders Investment and Trade), Dr. Rodolf Schosser and Dr. Simone Breitkopf (BPI), Mr. Waldemar Kuett (European Commission) and EICC Co-Chairman Mr. Ravi Mehrotra.

It was informed to the participants that in order to participate in the EICC activities in future, membership of the organisation; Corporate or Associate Membership is prerequisite.

### Telenor may ring India

Norwegian telecom group Telenor is said to be looking to enhance its presence in Asia which could include a possible entry into India's growing mobile market. Telenor has been present in Asia for more than a decade. As a long-term player, they said to have all ambitions of developing and increasing our presence in the Asian region. A team from Telenor was recently in India to assess such possibilities. Mobile telephony has grown rapidly in India, especially during the last three years, with India becoming the second-largest wireless market in the world. The number of wireless subscribers in the country has reached 250 million, making India the second-largest wireless market in the world. Currently, China is adding about 6-7 million new subscribers per month, India about 8-9 million and the US about 2-3 million. Mobile telephony has a positive impact on economic welfare by generating GDP; job generation (both in the mobile industry and the wider economy); productivity increases; and taxation revenue with mobile operators usually being a sizeable contributor. This sector has contributed $3.6 billion per year in import duties, licence fees, spectrum fees, and taxation revenues in India.With revenues drying up from mature markets, India's 297 million wireless subscriber base offers tremendous scope for growth. Telenor, the world's seventh largest telecom company, will be among the first European entrants to enter Indian telecom sector. The company added 30 million new subscribers last year and has a subscriber base of 143 million. With a host of new telecom players looking for global tie-ups with companies like Telenor and others for funds as well as technical know-how, India offers an ideal investment destination.

### India-German trade to cross 30 billion Euros by 2010

Trade between India and Germany is expected to cross 30 billion Euros in 2010 as the two countries expanded the areas of cooperation in various fields. The trade could touch 50 billion Euros in 2020 if India and Germany can engage in a fruitful partnership in various areas of research and development in science and technology. In the year 2007-2008, the figures of Indo-German trade stood at 12.07 billion Euros. India and Germany are also discussing creation of an International Centre for Excellence in Molecular Biology in India. Government of India is also deepening and strengthening its cooperation with the German Academic Exchange Service (DAAD), Humboldt Foundation, Fraunhoffer Society and (DFG)

Deutsche Forschungsgemeinschaft, which has recently opened its offices in Delhi. Apart from shared political, economic and social values, India considers Germany a very important collaborator in nation building. Germany is one of the largest economies of Europe. About 22 per cent of the Euro-zone economy is contributed by Germany. Indian entrepreneurs are aware of the fact that the nation offers access to 454 million consumers with a highly advanced infrastructure, roadways, railroads and state of the art communication networks.

### India refutes EU charge on wine import duty

Even as the European Union (EU) has said that it would demand WTO consultations with India on the tax regime on imported spirits and wines, the Indian government is confident that it has not violated any national treatment principle due to the levy of special duties on these products by Maharashtra and Goa. The EU also feels that Tamil Nadu has adopted a restrictive practice for imported liquor. Significantly, a similar complaint by the trade bloc at the WTO led to the elimination of additional Customs duty on imported liquor in 2007. Currently, India charges a basic Customs duty of 150 per cent on imported wines and spirits. After scrapping the additional Customs duty last year, the Centre had said that states could levy special taxes on imported liquor, which is equivalent to the state excise duties. Constitutionally, states are responsible for levying state excise duties on domestically produced liquor, but cannot apply the same to imported liquor. The EU has said that tax practices followed in Maharashtra, Goa and Tamil Nadu are in violation of the national treatment principle, according to which a country has to treat imported products on a par with those produced domestically. Legal experts say that in the next 60 days, India will have consultations on the issue with the EU at WTO. The Indian wine market is likely to grow to 1.7 million cases (one case has 12 bottles of 750 ml each) by 2010, with the present market being valued at $62 million.

### India-EU ink pact on civil aviation

India and the European Union (EU) during the EU-India Summit in France signed a landmark pact on civil aviation which will work like an 'open skies' agreement encouraging more airlines to offer services between the two continents. The Horizontal Civil Aviation Agreement that will effectively legalise 26 separate deals, which India had held with individual EU member states, was signed in France on 28th of September on the eve of their ninth annual India-EU Summit. The deal was inked by India's Ambassador to the EU Dr. Jaimini Bhagwati and officials from the French government and the EU's officials. The aviation deal described as a liberal pact puts an end to nearly six years of legal uncertainty which began when the European Court in November 2002, decided that bilateral deals on civil aviation services between EU member states and third countries discriminated against airlines from other EU states.

It does not in itself change the number or frequency of flights between the EU and India, but according to EU officials, it will encourage more airlines to offer services between the continents. Air India, Jet Airways and Kingfisher Airlines can hope to get more access to European destinations and EU carriers too can have better access to India. In a way, the pact will work like an 'open skies' agreement between India and the EU. The agreement between two of the world's largest trading partners provides far more flexibility than the air service arrangements being pursued by India with individual EU members.

The EU has similar agreements with China and the US. Currently, 26 bilateral air services agreements exists between EU members and India. The agreement would also allow people from either side to book an integrated ticket for travelling by different modes of transport such as road, rail, air and sea. It will also ensure technical cooperation between the two sides in areas like aviation safety, security and traffic management. The pact would remove nationality restrictions (from the EU side) in the bilateral air services agreements between EU members and India. This would allow any designated airline from the member states and India to operate flights to each other's side where a bilateral agreement with India exists and traffic rights are available. It is estimated that the US and the EU traffic constitutes about 30 per cent of India's total global air traffic, next to the Gulf (40 per cent). The monthly international traffic to and from India in April 2008 stood at 2.47 million, up 8.5 per cent over 2.28 million in the same period last year. India is one of the world's fastest growing aviation markets and it is of increasing strategic importance to the EU and its industry. Given the strong growth and infrastructure challenges facing India's aviation sector there are prospects of enhancing cooperation in civil aviation with India, an EU official said, adding the scope for cooperation is huge and will benefit both India and EU industry.