

## **EU-India Trade Agreement Position Paper of the European Federation of Pharmaceutical Industries and Associations (EFPIA)**

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### **Summary**

The Europe 2020 strategy acknowledges the critical role that EU trade policy has to play in stimulating growth, creating jobs and increasing prosperity for EU citizens.

The European Federation of Pharmaceutical Industries and Associations (EFPIA) sees an ambitious Free Trade Agreement (FTA) between the European Union (EU) and India as a significant opportunity to deliver on Europe 2020 targets by facilitating European companies' access to the Indian market while bringing major benefits to the fast-growing Indian economy.

European research-based pharmaceutical companies are already working closely with Indian partners at various levels. Over the past decade, EFPIA members have increased their investments in India, including in the areas of research and development and in the manufacture of active ingredients. EFPIA companies are working in partnership with the Indian government to improve the provision of healthcare. They have also demonstrated their commitment to sharing expertise and stimulating local innovation to begin to develop new medicines and make them available to the wider Indian population. In addition to the economic benefits it will bring for the EU and India, EFPIA members see an FTA with India as a way to further build on this collaboration.

However, to realise the full potential of this partnership in the medium and long term it is essential that India develops a more robust, stable and predictable legal framework for the protection of intellectual property rights (IPR). The Declaration jointly signed by European and Indian industries at the Business Summit last December states that IPRs are crucial to both India and the EU. EFPIA therefore supports the inclusion in the Free Trade Agreement of balanced provisions in this area, which can stimulate further investment in innovation by both European and local companies, while taking account of India's level of development. In this regard, EFPIA agrees with statements by the European Commission that inclusion of IPR provisions will not impede the Indian generic industry from supplying essential drugs.

### **Importance of intellectual property provisions**

For a knowledge-based economy, innovation, design and creativity are critical drivers for success and key to international competitiveness. It is in this field that Europe can demonstrate true global leadership.

To this end, the EU's trade policy should be particularly directed at ensuring that intellectual property rights of European innovators are well protected and enforced by our trade partners.

Not only will this ensure that Europe's trade in innovative products continues to grow, but it will enable major trading partners such as India to implement the appropriate policies to increase their own innovative capacity and contribution to the global economy.

India has many of the elements to act as a hub for investment in pharmaceutical research and development (R&D) and make a major contribution to tackling health challenges both domestically and around the world. These include consistent growth, a highly educated workforce and a developing science base.

The FTA can provide the platform for the next stage of India's development, by building incrementally on the existing legal framework for IPR. This will encourage the development of a research based pharmaceutical sector in India, through sustained investment by European companies and partnership between European business and local innovative companies.

Regulatory Data Protection is an essential legal mechanism to protect, for a limited period, huge investments in data necessary to bring a medicine to market. The absence of Regulatory Data Protection is a vital gap in India's intellectual property regime to promote pharmaceutical innovation, particularly when compared to both developed economies and other emerging economies such as China and Russia. EFPIA, therefore, stresses the importance of the inclusion of an effective Regulatory Data Protection framework in the final FTA.

### **Safeguarding access to essential medicines**

Concerns have been raised by certain groups about the potential impact of IPR provisions in the FTA on the production of essential medicines by the Indian generics industry.

However, EFPIA members firmly believe that an ambitious FTA will improve conditions for trade, investment and access to the Indian market, without affecting access to medicines.

At present, despite the presence of one of the world's leading generics industries, a large proportion of the Indian population still lacks regular access to essential medicines - all of which have no patent protection and can be widely produced in India.

While it is important that appropriate IP regimes are developed in Emerging Markets, industry must respond in a pragmatic, flexible and sensitive way. This must be the case as India transitions to a knowledge-based economy where the IP framework plays an important role. In

this context, EFPIA agrees with statements by EU and Indian negotiators that the provisions in the Free Trade Agreement will in no way limit India's ability to export life saving medicines.<sup>1</sup>

The European research-based pharmaceutical industry's commitment to improve access to medicines in India is demonstrated through numerous initiatives, sharing expertise and stimulating local innovation to being to develop new medicines and make them available to a wider Indian population. The conclusion of an EU/India FTA will not affect these initiatives. We believe that European and Indian companies are part of the solution to addressing unmet medical needs and global health challenges.

Pro-innovation policies and increased access to healthcare are not a contradiction in terms. On the contrary, they should go hand in hand for the benefit of future generations in Europe, India and around the world.

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## **About EFPIA**

EFPIA is the European pharmaceutical industry association with membership of 31 European national pharmaceutical associations and 40 leading companies undertaking research, development and the manufacture in Europe of medicinal products for human use. Through its membership, EFPIA represents over 2,200 companies committed to researching, developing and bringing to patients new medicines and vaccines that improve health and quality of life around the world.

The European research-based pharmaceutical industry represented by EFPIA provides significant investments in research and development and is one of the few remaining high technology industries in the EU to make a major contribution towards achieving the objectives recently set by the "EU 2020" strategy. The industry's contribution to Europe's economy amounts to:

- 17% of EU business R&D expenditure;
- 5.6% of total EU manufacturing exports;
- 3.5% of the total EU manufacturing added value;
- a positive trade balance of 39 billion Euros worldwide (excluding Switzerland);
- and employing over 633,000 people in Europe, including 113,400 skilled scientists and technologists specialised in R&D.

*EFPIA, March 2011*

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<sup>1</sup> Karel de Gucht, Anand Sharma joint op-ed, Business Standard, 13 December 2011 <http://www.business-standard.com/india/news/anand-sharmakarel-de-guchtpartners-in-trade-partners-for-growth/417950/>