EU-India FTA negotiations and access to medicines
Questions and answers

1. Will the Free Trade Agreement with India limit access to affordable medicines in developing countries?

The EU fully acknowledges India's right and capacity to manufacture and export life-saving medicines to other developing countries facing public health problems. The IPR provisions proposed in the EU-India FTA are not intended to weaken this.

Consequently, the EU has proposed a clause in the negotiations to ensure that nothing in the proposed agreement would limit India's freedom to produce and export life-saving medicines in accordance with the TRIPS Agreement and the Doha Declaration on the TRIPS Agreement and Public Health, notably through compulsory licensing.

2. Will provisions like data exclusivity delay the availability of generic medicines in India and in other developing countries?

Data exclusivity is important to take into account the fact that the development and marketing of a new medicine requires the originator to conduct extensive research and testing, which are very costly and often take more than 10 years to complete, and therefore deserve adequate protection as required by Article 39.3 TRIPS. Negotiations are ongoing on this issue with India. But the Commission is ready to show the necessary flexibility here, and fully take into account the specificities of the Indian legal system, the policy developments on this issue within India, its developing country status and the role it plays with regard to production of essential generics for the developing world.

3. The implementation of the TRIPS Agreement introduced a 20 year patent term for medicines in India. Is the EU seeking an extension of this patent term beyond what is required by TRIPS?

Patent term extension is a mechanism to address the issue of delays in the processing of marketing approval applications. Such a mechanism exists in certain countries including the EU to compensate drug innovators for long delays, during patent life, in the obtaining of marketing approval. As a result of these delays, the medicine is often available in the market only several years after the patent application has been filed. Such measure has been considered appropriate in the EU. It gives the right holder effective patent protection up to 15 years from the time the medicinal product first receives marketing authorization.

The issue was suggested for discussion in the FTA negotiations with India. If our bilateral discussions confirm that the processing of marketing approval applications in India is not a major concern, then the EU would not pursue the issue of supplementary protection any longer. Preliminary information indicates indeed that market authorizations in India are handled in an expeditious manner.

4. **Does data exclusivity hamper the effective use of a compulsory licence? In other words, does data exclusivity apply with regard to a compulsory licensee or would compulsory licences override data exclusivity?**

Data exclusivity will not hamper the effective use of a compulsory licence. The EU has proposed a clause that will guarantee that no provision of the FTA will prevent India from using the flexibilities contained in the TRIPS Agreement. More specifically, in case of conflict between data exclusivity rules and compulsory licensing, the latter would override the former.

5. **How will the Commission guarantee that legitimate generic medicines are not unfairly delayed when in transit through the EU?**

As regards enforcement and border measures, the agreement will not deal with generic medicines in transit. Regulation 1383/2003 concerning customs action against goods suspected of infringing certain intellectual property rights is currently being reviewed. The Commission is prepared to propose modifications to the Regulation that may be necessary to clarify the procedures relating to medicines in transit to ensure that generic medicines are not unnecessarily affected when merely transiting the EU. This principle will also be reflected in the IPR chapter to be agreed with India.

6. **What is the EU doing to stop fake medicines risking health of EU citizens or of citizen's in third countries?**

EU customs are empowered to detain goods suspected of infringing intellectual property rights under Regulation 1383/2003.

Moreover, EU law on pharmaceuticals obliges the importer of a medicine to do a quantitative and qualitative assessment of each batch of medicines, in order to ensure compliance with the EU laws on medicines. Every importer has to be holder of an authorisation and is subject to inspections. Recently, the Commission has proposed amendments to the EU law on pharmaceuticals to address in particular the prevention of the entry into the legal supply chain of medicinal products which are falsified in relation to their identity, history or source.

7. **Will the FTA contain other provisions that go beyond the TRIPS Agreement?**

The TRIPS Agreement dates back more than 10 years. In the meantime, new challenges have emerged (e.g. biodiversity-related issues, protection of traditional knowledge) and technical development has overtaken the agreement (e.g. digital environment). There is also a change as regards the economic importance of certain rights. There is for example a growing interest in designs and geographical indications.

Therefore where India and the EU have a shared interest in issues that complement or clarify the TRIPs Agreement, these will be included in the FTA.

8. Does the EU take into account the needs and level of development of its partners in negotiating IPR chapters in its FTAs?

Yes, of course. Whilst the overall objective is to improve the IPR situation in third markets to enable European companies to operate and compete in a legally secure environment, the EU is open to take into account the specific legal and economic situation of its trading partners.

9. What is the status of the negotiations with India? What is the timetable for conclusion and when would it come into force?

The 9th round of negotiations was held from 28-30 April, where both sides confirmed the objective of concluding negotiations swiftly – if possible even by the time of the EU-India Summit this year. Having said this, a number of issues still need to be solved and getting the substance right is the ultimate benchmark. As regards intellectual property, the negotiations are still at an early stage. It should be possible to advance quickly on IP given the high level of mutual understanding and interest in this issue.

10. What is the Commission doing to promote access to medicines in developing countries?

The Commission is doing a lot to promote access to medicines in developing countries. The EU is the biggest provider of resources to support health policies in developing countries.

Projects and programs funded by the EU in developing countries cover a wide range of activities: research, production, procurement and delivery, including quality control. The EU is associated with a number of WHO programmes for R&D and capacity building. The EU is also one of the oldest and biggest contributors to the Global Fund to Fight AIDS, Tuberculosis and Malaria and has donated €872m since 2002. Under its Co-operation Program of the 7th R&D Framework Program (2007-2013), the EU has allocated a total of €6.1b to health R&D worldwide.

More recently, in its Communication on EU role in global health, adopted on 31 March 31 2010, the Commission renewed its commitment and its call to EU Member States to strengthen the coherence between its policies with regards to development, and more specifically on drugs related issues (TRIPS, WHO Strategy, etc.).

The EU has actively participated in the WHO work to address urgent health needs in developing countries, in particular the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property. The EU has played a key role as facilitator in order to reach consensus on the most contentious issues.

The EU has also been active in the WTO debate on TRIPS and access to medicines and has been one of the main promoters of the Doha Declaration on the TRIPS Agreement and Public Health. The EU supports the flexibilities contained in the TRIPS Agreement. In order to fulfil its WTO commitments, the EU has implemented at the EU level the WTO decision allowing the manufacture

and export under compulsory licence of generic medicines to developing countries with health problems and without sufficient production capacities (Regulation 816/2006). The EU has also accepted the Protocol amending the TRIPS Agreement to make this solution permanent, and deposited its instrument of acceptance on 30 November 2007.

Beyond its international obligations, the EU has unilaterally set up a tiered-pricing mechanism for the supply of cheaper medicines to developing countries (Regulation 953/2003).
