



Solutions to improve access to medicines and biomedical innovation through EU trade and R&D policy

The European Union's (EU) free trade and research and development (R&D) policies promote excessive intellectual property (IP) protection. This approach jeopardises access to affordable, needed medicines and impedes needs-driven biomedical innovation.

Develop coherent policies across DGs that support development

Despite the Directorate-General (DG) for Trade being the Directorate in the European Commission (EC) responsible for leading the policy-making process around free trade agreements (FTAs) and other EU trade policies, it is imperative that concerns and proposals from other critical EU stakeholders are taken into account. This includes other DGs within the EC, especially DG Development, DG SANCO, the European Parliament (EP) and EU Member States (MS). This critical oversight is necessary to ensure that European public health, development and trade policies are coherent and not undermined, and benefit citizens in the EU and low- and middle-income countries (LMICs) alike.

Leave TRIPS-plus provisions out of EU trade agreements

TRIPS-plus provisions, such as patent term extensions and data exclusivity, extend monopoly protection and strengthen IP rights at the expense of access to affordable generic medicines. In particular, the EU should:

- **Not include TRIPS-plus provisions in FTA negotiations with Thailand.** The inclusion of TRIPS-plus provisions in this FTA would delay access to generic medicines and threaten the financial sustainability of universal health coverage in Thailand. Negotiations should remain on hold until a functional democratic government—and dialogue with civil society—is restored.
- **Protect the role of India as the 'pharmacy of the developing world'.** The EC should stop trying to impose TRIPs-plus provisions in FTA negotiations with India. It should also stop pressuring India to change its balanced IP legislation.
- **Not include TRIPS-plus provisions in trade negotiations with other LMICs**, such as Bolivia, the MERCOSUR region and Egypt.

Leave investment protection out of EU trade agreements

The inclusion of an investor-to-state dispute settlement (ISDS) mechanism in FTAs enables pharmaceutical companies to sue governments that take measures to improve access to medicines, or decide to exclude less effective treatments from reimbursement.

The EC should not include investment protection measures, including ISDS, in FTAs and bilateral investment treaties, particularly in its ongoing negotiations with the United States (through TTIP), India, Thailand, Egypt, the MERCOSUR region and Myanmar.

Ensure TTIP does not harm public health and become the new global standard

TTIP is an immense threat to European public health systems. It may increase the pharmaceutical industry's influence over pricing and reimbursement decisions and enable investment protection. This would limit the ability for EU Member States to implement measures that protect public health. TTIP, billed as "setting the path for global standards", could even have worldwide damaging repercussions for access to treatment.

The EC should immediately enhance the transparency of the negotiating process and ensure that TTIP will not jeopardise access to affordable medicines or limit public health policy space in the EU.

Do not impose strong IP enforcement standards on third countries

Far-reaching IP enforcement potentially 'chills' generic competition because it creates a high level of legal uncertainty for generic competitors. Moreover, IP enforcement can obstruct the import, transit or export of generic medicines.

In its recently published communication on the EU's IP enforcement strategy, the EC remains consistent with its hard-line approach to exporting strong IP enforcement standards to third countries. Such excessive enforcement provisions are also proposed in the new European trademark legislation and could be exported to LMICs, like India, Thailand and the MERCOSUR region, in ongoing FTA negotiations.

The EC should stop targeting countries, such as India, that have implemented TRIPS-compliant progressive IP policies through its watch list of "priority countries", and refrain from implementing financial sanctions on these countries as envisaged in this new EC communication. All in-transit enforcement provisions should be excluded from the new EU trademark legislation.

Support LMICs' use of TRIPS safeguards and flexibilities to protect public health

The EC and MS should encourage and support LMICs and least-developed countries (LDCs) in using TRIPS flexibilities. These may include compulsory licensing, narrowing the scope of patentability standards, and introducing other key public health safeguards. Use of these flexibilities would help guarantee access to affordable medicines, including newly patented, high-priced, life-saving drugs for hepatitis-C and cancer.

In particular, the EC and MS should support LDCs in any request to extend the TRIPS implementation transition period as long as they remain an LDC. They should also engage in meaningful technology transfer that allows LDCs to build a sound technology base.

Support the exploration of new models of biomedical innovation

Rather than extending market exclusivities through stronger IP protection in FTAs, the EU and its MS should support the exploration of new models of biomedical innovation that are responsive to public health needs and result in affordable medical products.

The EC and MS should ensure that innovation and biomedical knowledge, derived in whole or in part from publicly-funded health R&D, such as Horizon 2020 (including the European and Developing Countries Clinical Trials Partnership and the Innovative Medicines Initiative), results in public goods and medical products that are appropriate, affordable and accessible.

In particular, the EC and MS should implement and support non-exclusive licensing policies, data sharing, and new incentive mechanisms that de-link the costs of R&D from the final price of medicines. This could entail pilot programmes on innovation models that include innovation inducement prices, patent pools, open source research and product development partnerships.

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