THE TRUTH BEHIND THE SPIN

How the Europe-India Free Trade Agreement will harm access to medicines

India plays a crucial role in supplying the developing world with affordable quality medicines, but this is under threat. The European Commission (EC) is currently negotiating a free trade agreement (FTA) with India that includes a number of harmful provisions that could seriously hamper access to medicines across the developing world. In response to growing criticism, the EC issued a Q&A to defend its position[1] - but the EC misrepresents the real impact the FTA risks having.

In pushing an agenda that promotes the interests of its own pharmaceutical industry, the EC is ignoring the crucial role played by affordable quality generic medicines manufactured in India, and is actively undermining patients' access to newer essential drugs. The following highlights the truth hidden behind the spin in the 'Q&A' issued by the European Commission.

SPIN: The EC says that its policies will not weaken India's ability to produce and export affordable medicines.

TRUTH: There are three main aspects of the agreement that will have a chilling effect on the ability of Indian generics companies to produce and sell affordable, life-saving medicines across the developing world. These are:

(1) Delaying the registration of generic medicines through so-called 'data exclusivity' (DE): If India introduces DE, it would allow a pharmaceutical company to stop others referring to the data it generated on the safety and efficacy of a medicine for a period of up to ten years. Currently, when a generic manufacturer applies to register and sell a version of an already-registered medicine, they only have to demonstrate that their product is equivalent to the original.[2] The drug regulatory authority relies on the efficacy and safety data provided in the registration file of the original manufacturer. But this system is under threat.

Data exclusivity would prevent the registration of generic versions of a medicine for up to ten years. The only solution would be for the generic manufacturer to repeat the drug trials that the originator has done. This would be extremely costly. Plus, repeating clinical trials for medicines already proven effective is not ethical, as it means denying treatment known to be safe and effective from some patients (the control group), solely for the purpose of proving something that is already known.

If accepted by India, data exclusivity provisions will apply to all drugs – essentially creating a new patent-like monopoly by blocking the registration of generic medicines. Competition would be stifled even on older drugs which are not under patent and on new drugs which have been found not to merit patent protection.

As an example, a patent on nevirapine syrup to treat children living with HIV/AIDS was rejected by the Indian patent office, allowing generic producers to begin manufacturing right away. If DE had been in place, they would have had to wait up to ten years to be able to start producing this drug, even though it did not deserve a patent.

Despite the EU's assurances, studies from other countries show how harmful DE can be in terms of making medicines more costly. In Jordan, where data exclusivity was introduced as part of the US-Jordan FTA, a study found that of 103 medicines registered and launched since 2001 that currently have no patent protection in Jordan, at least 79% have no competition from a generic equivalent as a consequence of data exclusivity.[3] A study on the effects of DE in another free trade agreement negotiated by the European Commission shows that in Colombia alone, the introduction of a ten-year period of test data exclusivity would lead to an increase in medicines expenditure of US$340 million by 2030.[4]

For people who live without access to the medicines they need, a six to ten year wait until the DE term has expired can mean the difference between life and death.

The European Parliament in 2007 specifically directed the European Commission not to include requirements of data exclusivity and other TRIPS-plus measures in bilateral agreements with developing countries.[5] Yet the European Commission continues to ignore this specific direction and attempts to force India to choose between its ability to provide access to medicines and greater trade with the EU.

(2) Stopping the flow of generic medicines through border measures: In recent years, there have been nearly 20 incidents of legitimate generic medicines transiting through European ports being detained.[6] In each case, European customs officers, acting on the basis of European Customs Regulation (Council Regulation (EC) No 1383/2003), stopped the flow of medicines on the assumption that the drugs infringed a patent or a trademark. Now the EC is trying to impose rules such as these on India.

(3) Killing generic competition through a stricter enforcement of intellectual property: The EC is pushing for greater enforcement of IP through various channels. The EU FTA text seeks to have India incorporate different types of enforcement measures for private intellectual property rights owners.

One of the EC's demands is to introduce the mandatory use of court injunctions (court orders). When a patent or trademark dispute emerges between a generic and a patent-holding company, this would mean that the production of drugs by the generic manufacturer would have to stop, even before a case for infringement has been heard in court. The courts would therefore not be allowed to balance the constitutionally-enshrined right to health and access to medicines against the economic harm and compensation due to the rights holder if the case is proved.

In addition, the EC has failed to clarify whether it is seeking to have IP included in the investment measures of the FTA. This would open a whole new arena for litigation as soon as India adopted any regulation, injunction, administrative decision or legislation that favours patients over profits. A clear example of how companies can use a bilateral investment treaty to challenge government decisions related to public health on grounds of IP infringement exists. In February 2010, Philip Morris, the tobacco company, filed a case against Uruguay under a Switzerland-Uruguay Bilateral Investment Treaty in order to challenge Uruguay's decision to increase the size of warning labels on cigarette packets. Philip Morris argues that these measures infringe their trademarks and hamper their competitiveness in the Uruguayan market. The case is ongoing.[7]

WHAT THE EC NEEDS TO DO: The EC must stop pushing for data exclusivity to be included in the EU-India FTA; must stop interfering with the flow of generic medicines in transit; and must not include intellectual property in the definition of investment so that public health measures such as a compulsory licence or the refusal to provide data exclusivity cannot be linked to either the definition of 'investment' or be the subject of legal challenges by companies.

SPIN: The EC says data exclusivity is needed to compensate patent holders for their research and development, and that it is in line with existing international trade agreements.

TRUTH: India already does compensate patent holders for research and development. In 2005, the country introduced patents for medicines as a part of its membership of the World Trade Organization (WTO) – and the effects of this are already seen, with newer medicines already patented in India. Although this already poses significant threats to access to medicines across the developing world, the EC is now demanding additional terms that go way beyond India's obligations under the WTO TRIPS Agreement (Trade-related Aspects of Intellectual Property Rights).

Nowhere does TRIPS state that countries should provide exclusive rights to the originator over test data, and data exclusivity is not included in the TRIPS Agreement. In fact, as the TRIPS Agreement was being negotiated, the idea of including 'data exclusivity' provisions were specifically rejected.[8] Rather, TRIPS simply refers generally to the need to protect 'undisclosed test or other data' from 'unfair commercial use' and 'disclosure' (Art. 39.3). The TRIPS language makes it clear that countries can determine what constitutes 'unfair,' and that there are multiple approaches that countries can take to satisfy this mandate.[9] [10]

WHAT THE EC NEEDS TO DO: The EC must drop its demands for this backdoor monopoly protection.

SPIN: The EC says that it will guarantee that legitimate generic medicines are not unfairly delayed when in transit.

TRUTH: The EC is pushing for measures that do precisely the opposite. It is seeking to include civil trademark disputes in the FTA and elsewhere, not least in ACTA, the Anti-Counterfeiting Trade Agreement the EU is negotiating in secret.[11]

Civil trademark disputes – when one company alleges that a competitor is infringing its trademark because for example its packaging is too similar – are common. It is crucial that they be differentiated from *wilful* trademark infringements, where a company deliberately and fraudulently sets out to pass for something that it is not. But the European Commission is blurring that crucial difference and is pushing for provisions that include civil trademark disputes.

If the European Commission gets its way, customs officials could detain and even destroy allegedly infringing goods, without judicial review or even notification to the rights holder, on the mere basis of an assertion of a commercial trademark dispute. In practical terms, this could mean effective and safe medicines are stopped from being produced or are destroyed in order to protect company profits.

Crucially, these have been grounds for the detentions of generic drugs before: in Germany, a drug was detained on the basis of an alleged trademark infringement as it used the internationally-authorized generic name amoxicillin, which a customs officer deemed was too similar to the originator's brand name Amoxil.[12]

The EC says it is reviewing its customs regulations, but it has yet to make the results of its consultation public or provide details of how they will be amended.

WHAT THE EC NEEDS TO DO: The scope of provisions in the EU customs regulations, FTA and ACTA must be limited to wilful commercial scale trademark infringement - the fraudulent exact copying of labelling and branding where there is a potential threat to public health. Any broader definition will hamper access to generic medicines.

SPIN: The EC says it is trying to stop fake medicines that pose a public health risk for consumers

TRUTH: The spectre of harmful fake medicines is one of the concerns used to justify customs regulations and ACTA. Yet the real effect of such regulations and agreements is not to address fraudulent, unsafe, and ineffective medicines but rather to protect the commercial interest of multinational companies. Commercial trademark disputes – when companies argue over packaging that resemble each other, for example – do not pose a threat to public health: they are purely a commercial matter.

The sad truth is that provisions such as those the EC is pursuing would inhibit generic competition and increase drug prices. This in turn would actually encourage the introduction of fake medicines. The World Health Organization (WHO) has recognised that high drug prices are a cause of counterfeit medicines: patients demand low-cost alternatives, and counterfeiters respond.[13]

WHAT THE EC NEEDS TO DO: If the European Commission is serious about acting against unsafe medicines, it requires a public-health-focused global solution developed through a legitimate process, in which all countries are involved. Developing countries have asked that such discussions take place at WHO and other multilateral institutions rather than through a one-sided commercially-focused agreement amongst a few countries, negotiated behind closed doors. Adequate definitions of fake medicines and strengthening of drug regulatory authorities in developing countries would be important aspect to address the public health problem.[14]

SPIN: The EC says it supports the use of TRIPS flexibilities that ensure access to medicines and that the FTA will not hamper the effective use of a compulsory licence.

TRUTH: TRIPS flexibilities are lawful mechanisms that countries can use in order to ensure access to medicines is not blocked by patents and other IP rights. In today's post-TRIPS era, when medicines are being increasingly patented globally, the production, registration, supply, import and export of generic medicines will depend on countries' ability to use TRIPS flexibilities, such as defining a patent law that protects public health and using compulsory licenses to overcome patent barriers.

India has sought to limit abusive patenting, by not giving patents to companies that have made small changes to an existing drug that do not improve its therapeutic effect. But what gains this means for public health, the EC is now seeking to remove through the FTA.

Data exclusivity is specifically targeted at undermining India's patent law. Claiming that harm will be limited because data exclusivity can be lifted if a compulsory licence is issued ignores the fact that DE would have the greatest adverse impact in cases where there are NO patents on a medicine.

The European Commission continues to claim it respects the Doha Declaration on Public Health which allows the use of TRIPS flexibilities, but this is meaningless rhetoric given the TRIPS-Plus provisions that the EC continues to demand.

WHAT THE EC NEEDS TO DO: Stop pushing data exclusivity in the EU-India FTA. Stop giving the misleading impression that access to medicines is only dependent on the use of compulsory licences and stop undermining the right under TRIPS for countries to set own patentability criteria through backdoor attempts to create new monopolies.

SPIN: The EC says it is working to promote access to medicines in developing countries.

TRUTH: Yes, the EC is involved in a number of important initiatives, not least providing support to the Global Fund for AIDS, TB and Malaria (GFATM), and financing research and development globally. But the trade policies being pursued by the EC through the FTA and ACTA will entirely undermine the impact of these other initiatives.

Donor-funded treatment initiatives such as the Global Fund are dependent upon access to affordable generic medicines. A recent study in the Journal of the International AIDS Society finds that since 2003, 80% of donor-funded HIV medicines purchased for developing countries were supplied by Indian generic manufacturers.[15] Given the funding shortfall resulting from the latest GFATM replenishment round, there is a genuine fear that donor-funded programmes may not be able to maintain their current levels of treatment for 5.2 million people receiving treatment today, let alone to expand access to the nearly ten million people still on the waiting list who will die without access in the next two to three years.

WHAT THE EC NEEDS TO DO: The EC must stop undermining the very industry that, by providing quality medicines at an affordable cost, makes the global health initiatives the EC supports viable.

[1] EU-India FTA negotiations and access to medicines. http://trade.ec.europa.eu/doclib/docs/2010/may/tradoc_146191.pdf
[2] World Health Organization (2004). Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability. Geneva.
http://www.who.int/medicines/services/expertcommittees/pharmprep/QAS04_093Rev4_final.pdf
[3] Oxfam, (2007): All costs, no benefits: how TRIPS-plus intellectual property rules in the US-Jordan FTA affect access to medicines.
[4] Oxfam and Health Action International, (2009), 'Trading away access to medicines. How the European Union's trade agenda has taken the wrong turn.'
[5] European Parliament resolution of 12 July 2007 on the TRIPS Agreement and access to medicines.
http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P6-TA-2007-0353+0+DOC+XML+V0//EN

[6] Letter from Netherlands Ministry of Finance to Health Action International. 7 May 2009. http://www.haiweb.org/19062009/7%20May%202009%20Dutch%20government%20response%20to%20Freedom%20of%20Information%20request%20(EN).pdf

[7] Uruguay: Philip Morris files first-known investment treaty claim against tobacco regulations. March 3, 2010. http://www.bilaterals.org/spip.php?article16921

[8] The Use of Flexibilities in TRIPS. Musungu S, South Centre, and Oh C, World Health Organization. http://www.who.int/intellectualproperty/studies/TRIPS_flexibilities/en/index.html p65

[9] WHO Commission on Intellectual Property Rights, Innovation and Public Health (2006). Public health, innovation and intellectual property rights: report of the Commission on Intellectual Property Rights, Innovation and Public Health. WHO, Geneva. Available at http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf

[10] Correa C (2002). Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement. South Centre. Available at http://www.southcentre.org/index.php?option=com_content&view=article&id=68%3Aprotection-of-data-submitted-for-the-registration-of-pharmaceuticals-implementing-the-standards-of-the-trips-agreement&catid=41%3Ainnovation-technology-and-patent-policy&Itemid=67&lang=en

[11] Anti-Counterfeiting Trade Agreement. Informal Predecisional/Deliberative Draft: 2 October 2010. http://keionline.org/sites/default/files/actaoct2010.pdf

[12] IP Watch. Drug Seizures In Frankfurt Spark Fears Of EU-Wide Pattern. 5 June 2009. http://www.ip-watch.org/weblog/2009/06/05/drug-seizures-in-frankfurt-spark-fears-of-eu-wide-pattern/

[13] WHO (2010). What encourages counterfeiting of medicines? http://www.who.int/medicines/services/counterfeit/faqs/15/en/

[14] MSF (2010): Patients first: access to safe, quality and effective drugs. http://www.msfaccess.org/fileadmin/user_upload/medinnov_accesspatents/WHA%20Package%20Counterfeit%20FINAL%20April%202010.pdf

[15] Waning, Diedrichsen and Moon, (2010), 'A lifeline to treatment: the role of Indian generic manufacturers in supplying antiretroviral medicines to developing countries', Journal of the International AIDS Society.