The EU-India Free Trade Agreement

Concerns for access to essential medicines

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The Campaign for Access to Essential Medicines

•Médecins Sans Frontières (MSF) is an Independant international Humanitarian aid organisation that provides emergency medical assistance to populations in danger in more than 70 countries.

•In the field, MSF doctors are constantly frustrated by the lack of adequate medical tools to give quality care to the patients we treat.

•1999: Creation of the MSF Access to Essential Medicines Campaign

- **to improve access to existing medical tools (medicines, diagnostics, vaccines)**
- **to stimulate the development of urgently needed better tools for people in countries where MSF works.**

• Two major challenges :

- **the high cost of existing medicines => Response: challenge the high costs of existing drugs**
- **the absence of treatments for many of the diseases affecting our patients. => Response: stimulate research into new medicines for neglected diseases such as tuberculosis, sleeping sickness and malaria.**

High cost of existing medicines => Response: challenge the high costs of existing medicines

• Many medicines, in particular those that are new, such as HIV medicines, are too expensive for use in poor countries.

•Patent protection has increased in developing countries as impliment TRIPS agreement and this pushes prices up because patents provide a monopoly for the originator company for up to 20 years, blocking competition. Some newer HIV medicines already under patent in India.

• Competition is proven to be the most effective way to lower prices of medicines

• The European Union is negotiating a number of international trade agreements that contain Intellectual Property (IP) provisions that could harm access to medicines: a higher IP protection => less possibilities for generic industries to produces cheap quality essential medicines. One of these agreement is the EU – India Free Trade Agreement (FTA)

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Why are we concerned about the EU – India FTA?

•MSF relies on affordable generic medicines to treat people in more than 60 countries – over 80% of HIV medicines we use to treat over 160,000 people are from India. Without affordable generics, millions of lives saved over the past decade would otherwise have been lost.

•India is the pharmacy of the developing countries, previously because no drug was patented; this changed as India implemented the TRIPS agreement

•**but**, today, in line with WTO requirements, Indian patent law (section 3D) contains provisions that

- ➢safeguard against unnecessary patenting of medicines - especially for Fixed Dose Combinations' and child friendly formulations
- ➢allow for competition from generic companies.

Provisions within the EU-India FTA threatening access to medicines

1. Data Exclusivity
2. Excessively broad enforcement measures
3. Definition of investment - no answer
4. Border measures include civil trademark infringement (resolved WTO case - awaiting details)

1) Data Exclusivity (DE): What is it?

Definition: certain length of time during which the Regulatory Drug Authority (DRA) cannot rely on the originator's data in order to register a generic version of the same product. Manufacturers cannot sell medicines without authorisation.

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. The DRA relies on the efficacy and safety data provided in the registration file of the original manufacturer. This ensures that there is no unnecessary repetition of clinical trials which would be both unethical and economically costly.

Introducing DE would allow an originator pharmaceutical company to stop others (also the DRA) referring to the data it generated on the safety and efficacy of a medicine for a period of up to ten years.

DE is not required under the TRIPS Agreement. WHO opposes for developing countries. It's a TRIPS + provision.

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Data Exclusivity and access to medicines

DE will apply to all medicines even those which have been free of patent protection, so also those that are no longer under patent and on new versions of medicines which have been found not to merit patent protection.

The Commission claimed that harm will be limited because DE can be lifted if a compulsory licence (CL) is issued. This ignores the fact that DE would have the greatest adverse impact in cases where there are NO patents on a medicine.

Commission recently claimed it will not oppose some forms of exceptions to DE for public health's needs. Not clear how this would work + ignores fact DE is not required under TRIPS.

With DE, generic manufacturers will have two choices:

1. **generate their own test data to register the medicine => huge costs + ethical concerns => This would deter generic companies from marketing affordable medicines.**
2. **wait the DE has expired - even if there is no patent protection - which means that the medicine will remain unaffordable for a longer period of time.**

So *de facto*, DE creates a new patent-like monopoly.

Data Exclusivity seen by the WHO

"From the perspective of public health and access to medicines, it is preferable not to grant data exclusivity. Moreover, there is no requirement under international law that countries grant data exclusivity; countries only have to provide for data protection".

"TRIPS plus' requirements have at times been incorporated in bilateral or regional free trade negotiations, in bilateral investment agreements and in other international agreements and treaties. From the perspective of access to medicines, this is a worrying trend; countries should therefore be vigilant and should not 'trade away' their people's right to have access to medicines".

(Briefing note on Access to medicines, March 2006)

2) Excessively broad enforcement measures

The Commission demands to introduce limits on use of court injunctions.

⇒ when a patent dispute emerges between a generic and a patent-holding company, the production of the generic drugs 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 right to health against the economic harm and compensation due to the rights holder if the case is proved.

3) Definition of investment

We received the information that the **definition of investment** in the draft negotiating text has been extended to include IP.

⇒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.

Until today, we have not received any clear response from the Commission on this point.

Thank you