



## Response to European Union's submission on South Africa's Draft National Intellectual Property Policy

July 1<sup>st</sup>, 2015

### I. Data protection

*The EU submission states: "the protection of such data... is an international obligation".<sup>1</sup>*

Data protection seeks to prevent medicine regulatory authorities from using clinical trial data of originator medicines for the registrations of generics during the period of data protection.

- **TRIPS Article 39.3:**

*Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data **against unfair commercial use**. In addition, Members shall protect such data against disclosure, except where **necessary to protect the public**, or unless steps are taken to ensure that the data are protected against unfair commercial use.<sup>2</sup>*

The mandate of drug regulatory authorities is to ensure the efficacy and safety of medicines. The use of test data to carry out these functions does not entail unfair commercial use. MSF would like to recall that the original negotiations of the TRIPS Agreement specifically avoided expanding "data protection" to include "data exclusivity".

Moreover, requiring generic companies to develop their own test data by repeating trials would violate medical ethics. Prescribing placebos or sub-standard alternatives for patients (as is done in the ordinary course of phase III clinical trials), despite proven knowledge that an effective treatment is available would be unethical and in clear violation of the Helsinki Declaration on Ethical Principles for medical research on human subjects.

Finally, if "data protection" is interpreted and implemented as "data exclusivity" it can severely and negatively impact on access to affordable, generic medicines. This is because data exclusivity can block the introduction on the market and the use of generic versions of medicines, that do not have patent protection as the following example illustrate:

- **The Jordan Example:**

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<sup>1</sup> Letter addressed to Mr. Lionel October from Director for Services and Investment, Intellectual Property and Public Procurement, Mr. Rupert Schlegelmilch, EU Directorate General for Trade, October 18 2013, Annex p. 3.

<sup>2</sup> Accessible at: [https://www.wto.org/english/docs\\_e/legal\\_e/27-trips\\_04d\\_e.htm](https://www.wto.org/english/docs_e/legal_e/27-trips_04d_e.htm)

A 2006 study by Oxfam showed that of the 103 medicines registered and launched since 2001 that had no patent protection, at least 79 per cent had no competition from a generic equivalent as a direct consequence of data exclusivity. A more recent analysis by the Medicines Transparency Alliance estimates that delayed market entry of generics resulting from the TRIPS-plus requirements in the US-Jordan FTA cost consumers \$18 million annually.<sup>3</sup>

The concern about “data protection” being interpreted as meaning “data exclusivity” has also been highlighted by the World Health Organisation’s (WHO) Commission on Intellectual Property, Innovation and Public Health:

“If the patent period has expired, or there is no patent on the product, this sui generis data exclusivity may act independently of patent status to delay the entry of any generic companies wishing to enter the market. This is because the regulators cannot use the data in the period of protection to approve a product, even if the product is demonstrated to be bio-equivalent, where required. The only alternative for a generic company would be to repeat clinical trials, which would be costly and wasteful, and would raise ethical issues since it would involve replicating tests in humans to demonstrate what is already known to be effective. These sui generis regimes, which provide for data exclusivity need to be clearly differentiated from the TRIPS agreement’s requirement for data protection”.<sup>4</sup>

## II. Patent extensions

*The EU submission states: “Patent term extension is a tool to compensate for any excessive delay in granting the first marketing approval in a country, which often lead to a reduction of the effective patent term”.<sup>5</sup>*

Patent extensions seek to extend the life of patents to compensate for regulatory delays. However, patent term extensions are not required under TRIPS and therefore constitute TRIPS plus measures that would reduce access to affordable medicines in South Africa.

We are aware of significant delays in the registration process of medicines and understand the concerns in this regard. But this does not provide a basis for patent extensions. Extending the life of a patent as a result of regulatory failure punishes the public without addressing the root cause of the problem.

Instead, we submit that the focus should be on what legislative and/or other measures are necessary to ensure that the regulatory body of South Africa (the Medicines Control Council (MCC), which is transitioning to the South African Health Products Regulatory Agency (SAHPRA) discharges its statutory mandate efficiently and effectively and to strengthen its ability. What is necessary to address the delays are public health-friendly measures that address the underlying problem, not commercial subsidies that increase medicine prices and limit the ability of the government to make the right investments to strengthen SAHPRA.

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<sup>3</sup> All costs, no benefits: How TRIPS-plus intellectual property rules in the US-Jordan FTA affect access to medicines, Briefing Paper, Oxfam International, 2007. Full report available at:

<https://www.oxfam.org/sites/www.oxfam.org/files/all%20costs,%20no%20benefits.pdf>

<sup>4</sup> Public health, innovation and intellectual property rights, Commission on Intellectual Property Rights, Innovation and Public Health; WHO, 2006, p. 125; Full report available at: <http://www.who.int/intellectualproperty/report/en/>

<sup>5</sup> Letter addressed to Mr. Lionel October from Director for Services and Investment, Intellectual Property and Public Procurement, Mr. Rupert Schlegelmilch, EU Directorate General for Trade, October 18 2013, Annex p. 3-4.

MSF notes the efforts of the EU to improve the regulatory system and reduce delays to registration as a way to improve access to medicines.<sup>6</sup> MSF would however underline the importance of any regulatory systems strengthening being carried out independently of any private or commercial interest, including but not limited to intellectual property measures, and prioritising the availability of safe, efficient and quality-assured products with public health significance.

### **III. Border measures**

*The EU submission states: “The EU, together with many other [World Customs Union] members, including developing countries, considers that IPR border enforcement by customs is an important element in the fight against IPR infringements.”<sup>7</sup>*

Border enforcement measures generally allow customs authorities to detain shipments of medicines on the grounds of suspected IPR infringement. However, originator companies commonly use trademark infringement disputes to prevent competitors from entering the market. Originator and generic medicines often have similar names, shapes and colours. Previous shipments of generic medicines in the EU that did not infringe intellectual property rights have been seized by European customs officials on the grounds of suspected infringement. EU customs officials have also seized medicines in-transit in the EU on the grounds of patent infringement, even though both the sending country (in particular India) and the receiving country did not have patents on the relevant product (whereas there was a patent on the product in the EU). Such seizures of goods-in-transit represent an unacceptable expansion of the territorial enforcement of a patent that limits the free movement of generic medicines and generic competition.

Seizure of medicines for suspected IPR infringement could interrupt flows of medicines to South Africa, as well as MSF’s medical programmes across the continent. MSF is disappointed to note that the EU are planning to introduce additional border measures, with respect to trademarks, that will further increase the risk of confusing legitimate generic medicines with what the EU calls counterfeit medicines, thereby putting up barriers to the movement of medicines to developing countries and patients in needs.

- **UNDP Report ‘Using Law to Accelerate Treatment Access in South Africa’ (2013):** *“TRIPS require criminal remedies and border measures, only in the case of “wilful” “trademark counterfeiting” on a “commercial scale”. The WTO Dispute Settlement Body has distinguished between trademark infringement and trademark counterfeiting, noting that counterfeit trademark goods are defined in TRIPS as those that bear an identical mark or one that cannot be distinguished in its essential aspects from a trademark”.*<sup>8</sup>

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<sup>6</sup> South African Government News Agency. Govt to establish Institute for Regulatory Science. 18 February 2014. Accessed at: <http://www.sanews.gov.za/south-africa/govt-establish-institute-regulatory-science>

<sup>7</sup> Letter addressed to Mr. Lionel October from Director for Services and Investment, Intellectual Property and Public Procurement, Mr. Rupert Schlegelmilch, EU Directorate General for Trade, October 18 2013, Annex p. 6.

<sup>8</sup> Using law to accelerate treatment access in South Africa - an analysis of patent, competition and medicines law, UNDP, 2013; p 79. Full report available here: [http://www.undp.org/content/dam/undp/library/hiv/aids/English/using\\_law\\_to\\_accelerate\\_treatment\\_access\\_in\\_south\\_af rica\\_undp\\_2013.pdf](http://www.undp.org/content/dam/undp/library/hiv/aids/English/using_law_to_accelerate_treatment_access_in_south_af rica_undp_2013.pdf)

The new EU trademark regulation which introduces IP enforcement on goods in transit in the EU does not mandate that customs officials to take either “wilful” nor “commercial scale” into consideration when implementing the law.

#### **IV. Pirated and counterfeit goods and health**

*The EU submission states: “Available evidence suggests that falsified and other substandard medicines, meaning those that are not approved under a regulatory system as being safe and effective, are most prevalent in countries which have weak regulatory and enforcement frameworks”.<sup>9</sup>*

- **WHO definition of counterfeit medicines:**

"A counterfeit medicine is one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging."<sup>10</sup>

Ensuring that medicines are safe and effective is of critical concern to MSF. The regulation of medicine, to ensure safety and efficacy, is in South Africa dealt with by the Medicines and Related Substances Act and overseen by the Medicines Control Council (MCC), which is evolving to become the South African Health Products Regulatory Authority (SAHPRA).

It is important that the difference between “counterfeit medicines” that misuse a properly registered trademark, “falsified or unregistered medicines” that mislabel the ingredients and “substandard medicines” that do not meet applicable safety, efficacy and quality standards is recognized. The problems and challenges that each category poses require very different solutions. The Submission’s conflation of the various categories is unfortunate and wrongly assumes that IP enforcement is appropriate for dealing with all categories.

“Substandard medicines” for example, are genuine medicines produced by manufacturers authorized by the national medicines regulatory authority, which do not meet quality specifications set for them by national standards. They can therefore be both originator and generic medicines and an IP enforcement framework has no relevance or use for combatting this category.

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<sup>9</sup> Letter addressed to Mr. Lionel October from Director for Services and Investment, Intellectual Property and Public Procurement, Mr. Rupert Schlegelmilch, EU Directorate General for Trade, October 18 2013, Annex p. 8.

<sup>10</sup> What are Counterfeit medicines?, WHO, available at: <http://www.who.int/medicines/services/counterfeit/faqs/03/en/> (accessed on 29/6 2015)