

SUBMISSION OF CONTRIBUTIONS

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• Section 1: ABSTRACT: Briefly describe your contribution: (limit 300 words)

This contribution is addressed to the United Nations Secretary-General's High-Level Panel on Access to Medicines call for contributions. While the call is open enough to provide for a wide range of contributions, we focus on an aspect of the debate that is not much discussed by the available literature: the responsibility of the private sector for the systematic gross-violation of human rights related to the lack of innovation and access to health technologies, specially through the abuse of the patent system.

The debate around business and human rights has recently grown within the UN system, as well as the recognition that there is a lack of existing mechanisms that can be used to remedy human rights violations committed by the private sector. There is an urgent need that companies can also be held accountable for systematic violations of human rights, including in the access to medicines area. This contribution will be, therefore, about the need to establish mechanisms that could hold pharmaceutical companies accountable for their human rights violations.

We first discuss the right to access medicines as an element of the the right to health; then we address the systematic violation of this right by pharmaceutical and biotechnology companies, followed by a brief presentation on the obstacles faced to hold companies accountable for violations of human rights and finally we address the need to create an international legal framework that could make transnational companies (TNCs) responsible for the violation of human rights. We call on the UN High-Level Panel on Access to Medicines to recommend the creation of a binding instrument that has the potential to hold companies accountable for human rights violations, as well as monitoring of the Intergovernmental Working Group for the Treaty on TNCs and other businesses in the context of Human Rights.

• Section 2: YOUR CONTRIBUTION (limit 3,000 words)

Introduction – Statement of the problem

The right to health is a fundamental part of human rights and also a part of the right to an adequate standard of living. However, the right to health is still far from assured for a substantial part of the world's population. The right to health is not fulfilled when access to essential medicines is not implemented. When a human right is violated systematically and leads to loss of

work capacity, underdevelopment and death to people in several parts of the world, it is necessary to undertake review measures, punishment and reparation, which should be a matter of concern and action of governments and multilateral organizations. The right to health (and in some cases more broadly the right to life) implies the action or inaction of multiple actors, beyond individuals and States. Among them are the pharmaceutical companies.

This contribution aims to bring attention to the imperative need to put private companies in the lights, as they are also responsible for systematic violations of human rights related to lack of access to medicines. The warranty of impunity backed by the legal obstacles to accountability of human rights violations by the private sector and the absence of appropriate instruments to mitigate and repair the violations is a strong barriers to the achievement of universal access to essential medicines and therefore the implementation of the Sustainable Development Goals by 2030.

It is important to emphasize that the right to health is not only a programmatic long-term goal. One must take into account the need for immediate satisfaction of health needs, imposing emergency obligations of States, even if considering budget constraints. The interrelationship and interdependence of the various human rights require the observance of the right to health not only as an end in itself but also as it comprises and it is related to other human rights such as the right to life, work, water, and development, among others.

It is clear the responsibility of States to respect, protect and fulfill the right to health and, therefore, also provide essential medicines. However, it is necessary to advance the recognition of the role and responsibility of the private sector in the respect, protection and fulfillment of the right to health. More than that, it is crucial to implement forms of reparation in the event of rights violations perpetrated by other parties in addition to the States. In this document, we must pay attention particularly to pharmaceutical companies, given their crucial role in access to medicines.

Impact on remedying policy incoherence

It is well known that the application of human rights obligations to non-state actors, such as pharmaceutical companies, is still an unsolved matter in the context of international law (1). In the classical conception, it is generally the States that have to comply with respect for human rights. Nevertheless, in recent years we have seen increasing pressure for the recognition of non-state actors, such as corporations, as holders of human rights obligations, with clear responsibilities (2).

Another important aspect is the decisive role of companies in the globalized world. Some, often, are more powerful than entire States. Just as an illustration, in 2006 the hundred largest companies in the world had about a third of global GDP (3). However, the decision-making power is often diluted among several legal entities, affiliates and subcontractors, leaving them with a comfortable and convenient anonymous face.

All this economic power translates into political power. Powerful companies, especially those that for some reason are monopolists in the market, have an enormous capacity to influence States. It is well known that in the field of access to medicines the practice of monopoly and the search for its maintenance is a practice and not an exception, given its direct connection with the ownership of intangible assets through intellectual property rights.

Non-state actors, whether they act along with States or by their own, that violates human rights must be held accountable. The current international legal framework is not adequate and is far from sufficient to generate this responsibility and compensate victims of human rights violations perpetrated by companies. In other words, private businesses should not be alien and should not be protected from the obligation to respect human rights and human dignity and therefore there is an urgent need to adapt the international legal tools so that it is in line with the reality of current social dynamics.

Impact on public health

Systematic human rights violations by pharmaceutical companies

Pharmaceutical companies are key actors in the field of development and distribution of medicines and health technologies in the world. Therefore, they are involved in many crucial decisions: elect disease and target molecules (define priorities in public health); conduct and/or finance clinical trials (involving a complex skein of rights with strong ethical implications); are responsible for quality issues of drugs distributed to the public (shared responsibility for their supervision with state agencies); pressure and lobby States, multilateral organizations, health professionals and even competitors to advance their interests in domestic and international level; file for registration of medicines according to their discretion; set high selling prices; just to name some actions with direct impact on human rights and on public health. In all of the examples above, human rights violations may occur, both directly and/or with the connivance of state through actions or omissions.

Space limitations prevent us from enlisting examples of violations perpetrated for each of the above elements. However, it seems important to illustrate with concrete cases the enormous responsibility involved in the pharmaceutical field and the scope of human rights violations that can be performed by these companies.

As discussed above, access to medicines is a key component to the fulfillment of the right to health, and in some cases to the right to life. The lack of access may have consequences that can be classified as gross human rights violations that cause intentionally great suffering or serious injury to mental or physical health of the population, especially the most vulnerable. Acts of such a category of gravity should be subject of tools at its height, being unacceptable that they still remain in the field of voluntariness, as discussed below.

- Innovation and Intellectual Property: excluding millions of people from the right to health

In general, companies advocate that their role is to innovate and develop medicines and that such developments imply high costs. Therefore, they need monopolies to recover investments. The monopoly in the pharmaceutical field is guaranteed by the protection of IP via patents, withdrawing medical technologies from the public domain for a certain period of time. This system directly impacts the definition of priorities in research and development, given that it is a clearly a market-driven system.

There are lots of public health implications on this. Evidences shows that the IP system failed to provide the necessary health innovation for the largest part of global disease burden (4, 5) that simply do not constitute a profitable market for transnational companies (TNCs). When the

technologies are developed, treatments under patent consume a large proportion of national health budgets forcing governments to ration treatment, jeopardising universal access programs and diverting resources that could be spent on R&D for other diseases.

A recent example of lack of prioritization of health needs is the diseases transmitted by the *Aedes Aegypti* mosquito, especially dengue fever and zika. Reports of the Pan American Health Organization (PAHO) show that first dengue epidemic in the Americas occurred in Peru, at the beginning of the 19th century. After, the mosquito has become the villain of health, being a vector responsible for other diseases, including the zika virus. These, among many other diseases, have never been considered a priority in the development of drugs and vaccines not because they did not affect a large number of people but because they did not affect people in rich countries. The discretion of the companies to choose targets in health, relegating millions of people to suffering as result of obsolete therapies or no therapies at all often occurs. Even worse, it is naturalized with the justification that companies are profit-driven and not health-driven. In these cases, human rights are never taken into account.

The monopoly based-profit driven model of innovation also discourages the timely development of best possible treatments. "Activists and the scientific community have known about the potential benefits of TAF, over those of TDF, for twelve years; it is disappointing that its clinical development was delayed until the twilight of TDF's patent protection." (6). Although TDF is the backbone of HIV treatment programmes, its liver and kidney toxicity concerns were insufficient to prompt Gilead towards the early development of TAF, thus having deliberately endangered the lives and health of millions of PLHIV. For those co-infected with HepatitisC, Gilead's monopolistic moves have been even more costly as they are more likely to suffer renal failure with TDF-based regimens and would have better tolerated TAF-based regimens. Gilead's deadly game of monopoly for people living with Hepatitis C continues with its refusal to collaborate on a possible treatment in order to maintain the HCV market entirely for its own medicines.

Another element that is directly related to access to medicines are the extensively documented high prices charged because of patents, which allow monopolistic practices. The entry of medicines in the trade arena and the wide global spread of pharmaceutical patents have their origin in the Agreement on Trade-Related Aspects of Intellectual Property Rights. The TRIPS Agreement got in history as one of the most controversial components of the of the World Trade Organization (WTO) system. Approved 20 years ago under unbearable pressure from developed countries, it resulted in one of the most inequitable international agreement currently in force.

The TRIPS Agreement established high standards of intellectual property and perhaps this is the reason why the pharmaceutical industry is the most profitable industry in the world. Pharmaceutical companies operate with a profit margin of around 18.5% of sales, while in other industrial sectors' margin is approximately 3.3% (7). Thus, even if the need to have profit for return of investments could be justifiable, this level of such high profit is not. Specially, when millions of people around the world have poor health condition or even lose their lives because they cannot pay for an existing product that is sold at exorbitant prices to generate exorbitant profits for the pharmaceutical industry. WHO estimates that deaths of 18 million people, 1/3rd of all deaths, are caused by treatable medical conditions (8) and about 100 million people globally are pushed below the poverty line due to healthcare expenditure (9).

A clear example comes from Hepatitis C. In 2015, a new treatment was released: sofosbuvir. Gilead had its patent application granted in the US, which allowed the company to stipulate the price under monopoly conditions: "the \$1,000 pill". The three-month treatment course is being marketed in the US for \$84,000, a price that absolutely excludes millions of people from accessing the drug. The issue becomes even more dramatic by knowing the extent of Hepatitis C epidemic worldwide - roughly 185 million people or 3% of the world's population - and the production cost of the 12-week treatment estimated by University of Liverpool: between US\$68 and US\$136 (10). In Brazil, estimates, point that it would be necessary more than 11 billion dollars to provide sofosbuvir to all people living with hepatitis C in Brazil, more than double of the current available budget to purchase all the medicines distributes in the public health system (11). Although recurrent argument of pharmaceutical industry, the need to recover investments in R&D does not stand ahead data. According to a study at Columbia University, it was invested between 300 and 500 million dollars to develop sofosbuvir. Recent estimates indicate that Gilead has earned only on sales of sofosbuvir medicine in only one country (the US), more than 15 billion dollars in one year (12).

The logic of recovering R&D costs with remuneration obtained by commercialization of products with exclusive rights is the very basis of the IP system; therefore it is not possible to think of solutions within the system to solve the problem of access and profit-driven innovation. However, beyond the very nature of the system, its current practice is also permeated by abuses, such as underserved protection extension.

- Drugs quality and ethical abuses

Multiple cases have occurred throughout the history of pharmaceutical companies practices that led to disability, chronic illness and death, a practice that have been characterized as a case of "institutional corruption". According to LIGHT et.al., an extensive range of studies document strategies by which pharmaceutical companies hide, ignore or misrepresent evidence on new drugs; distort medical literature; and misrepresent their products to prescribers (13).

In 2008, GTPI denounced the pharmaceutical company Boehringer Ingelheim to the Permanent Peoples' Tribunal (TPP), accusing it of violating the right to health of the Brazilian population and ethical research standards in humans (Declaration of Helsinki) for its refusal to register the antiretroviral tipranavir, which was subject on clinical trials in Brazil. The Brazilian population were fit to undertake the risks of developing the drug, but not to benefit from it (14).

Furthermore, most "new" products marketed are, in fact, imitation products (me-too), namely molecules equivalent to those already on the market. Most R&D resources are directed towards the development of therapeutically similar drugs, which usually involves less risk and lower cost to producers. Pharmaceutical companies actually direct only 1.3% of its net revenue for the discovery of new molecules (13).

Impact on human rights

Corporations: the freedom to violate

In June 2011, the United Nations Human Rights Council (UNHRC) approved by consensus the Guiding Principles on Business and Human Rights prepared by John Ruggie. Essentially, the

guidelines foresee that companies should respect human rights and this means that they must avoid infringing human rights and address the negative impacts on human rights in which they have some involvement. The report also predicted that the responsibility to respect human rights requires companies to avoid their own activities generate negative impacts on human rights and confront these consequences when they do occur. The same Professor John Ruggie was one of the main architects of the Global Compact, launched in 2000 and today is considered the biggest initiative of Corporate Social Responsibility (CSR) in the world with more than 7000 companies. The Global Compact was designed as a learning forum for the promotion of socially responsible practices in the areas of human rights, and in his own words "is the archetype of voluntarism."

It does not seem reasonable that the debate on human rights and business follow in arrays as loose and elastic, characterized by voluntarism. In addition, this framework does not compel companies to repair human rights violations and it works, in the end of the day, as corporate advertising tool. To respect human rights should not be a slogan.

Something must be absolutely clear when addressing the business and human rights topic, applying to pharmaceutical companies: all victims of human rights violations have the right to an effective remedy, this is a maximum of human rights legislation. The right to an effective remedy is pacified in several international treaties as well as customary law. This implies: equitable and effective access to justice; adequate compensation, effective and easy to damage suffered (restitution, compensation, rehabilitation, satisfaction and guarantees of non-repetition) and access to information concerning human rights violations and reparation mechanisms. However, many obstacles are placed to the scope of an appeal in case of rights violations by companies, especially but not only, transnational corporations.

Some of the obstacles are:

- States have a duty to protect its people from abuse by companies. The language proposed in the s Guiding Principles of John Ruggie and incorporated by the Inter-American Court of Human Rights has called it 'Due Diligence'. However, as noted above, non-state entities are often more powerful than States. So how to ensure that due diligence will be made? Moreover, on several occasions companies and states violate conjugated and accomplice way, being a *longa manus* one another.
- Lack of clarity about who violates and who responds, large companies operate regularly through subsidiaries, sub-contractors, contracting chains, associations, cooperatives, conglomerated companies, etc. In practice, the tangle of legal personalities prevents the accuracy accountability for violations.
- Legal impediments to filing extraterritorial legal action: business groups can run away from answering for violations committed in a country given that its headquarters may be beyond the boundaries of where the violation happened. The transnational nature of a company should not be a blanket of impunity and build walls to prevent the access of victims to reparation. However, this happens routinely.

Implementation

The urgent need to advance international law

In order to advance on the fulfillment of the right to health and access to medicines, there is a need to address one of the supporting pillars of their violation: corporate impunity. It is urgent to build the real possibility that pharmaceutical and biotechnology companies find themselves compelled to respect human rights and that there is a sufficiently robust legal and judicial framework allowing reparations for victims. This necessity has also a preventive effect, since the certainty or high probability of impunity generates the maintenance of violations and perpetration new violations.

We urge the High-Level Panel on Access to Medicines to adopt the following recommendations (15):

- To follow the work of the Intergovernmental Working Group for the Treaty on TNCs and other businesses in the context of Human Rights
- That the UN system formulates and that states adopt a Binding Treaty that will hold companies accountable for human rights violations, including solutions to many current obstacles faced for effective access to resources for victims;
- That the treaty contains, among other points: the obligation of developed countries - where companies have their headquarters - to prevent the adoption of double standard regarding respect for human rights;
- That all companies respect human rights broadly; that the legally binding international instrument reaffirm the hierarchical superiority of human rights standards on other international treaties, including free trade and investment;
- That the binding instrument establishes civil and criminal liability of companies and their directors as well as joint and several liability of its subsidiaries, providers, licensees and subcontractors; and
- To recommend that the United Nations system working to establish mechanisms at the international level to enforce the treaty and control their application.

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