Open-ended intergovernmental working group on transnational corporations and other business enterprises with respect to human rights

Second session, 24 – 28 October 2016

FORM for NGOs and other relevant stakeholders submitting a written contribution

Please note that the written contribution is formatted and issued, unedited, in the language(s) received from the submitting organization (it should be submitted in one of the official UN languages).

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Please fill out **this** FORM and CHECKLIST to submit your written contribution and send it to the address indicated below. Your information goes after each arrow.

1. Please indicate the contact information for the representative submitting the written contribution (i.e. name, mobile, email) here: Pedro Villardi, (+55) 21 9 9438 0399, pedro@abiaids.org.br

2. (a) If this is an individual contribution, please indicate here your organization's name (kindly state in brackets whether your organization has ECOSOC consultative status (i.e. General, Special, or Roster).

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3. Indicate here any non-ECOSOC NGO(s) supporting the joint contribution (they will appear as a footnote to the title – unless it is a joint contribution from non-ECOSOC stakeholders only):
Organizations of the Latin American Network for Access to Medicines (RedLam):

- Brazilian Interdisciplinary AIDS Association (ABIA), Brazil;
- Grupo Efecto Positivo (GEP), Argentina;
- Fundación IFARMA, Colombia;
- Acción Internacional para la Salud, Peru.

4. Indicate the TITLE for the written contribution (in original language) here: 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.

Please make sure that:

☐ The written contribution is in MS WORD document format (Font Times New Roman 10; no bold; no underline; no italics).

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- Section 1: ABSTRACT

1. This contribution to the Intergovernmental Working Group on Transnational Corporations and Other Business Enterprises with Respect to Human Rights will focus on the responsibility of the private sector for the systematic gross-violations of human rights related to the lack of innovation and access to health technologies, particularly through the abuse of the patent system.

2. The debate around business and human rights has gradually 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 be held accountable for systematic violations of human rights, including in the access to medicines area. This contribution will address, therefore, the need to establish mechanisms that could hold pharmaceutical companies accountable for their human rights violations.

3. We first discuss the right to access medicines as an element of the right to health. Secondly, we address the systematic violations of this right by pharmaceutical and biotechnology companies. Thirdly, we briefly present the obstacles faced to hold companies accountable for violations of human rights. Finally, we reinforce the need to create an international legal framework that could make transnational companies (TNCs) responsible for the violation of human rights.

- Section 2: CONTRIBUTION

Introduction – Statement of the problem

4. The right to health is a fundamental human right and 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. Access to medicines is one of the essential elements in achieving the full realization of the right to physical and mental health. The right to health implies on the action or inaction of multiple actors, beyond individuals and States, including pharmaceutical companies.

5. The warranty of impunity backed by legal obstacles to accountability of human rights violations by the private sector and the absence of appropriate instruments to mitigate and repair the violations represents a strong barrier to the achievement of universal access to essential medicines.

6. The right to health is not only a programmatic long-term goal; it requires 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 as not only 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.

7. It is clear the responsibility of States to respect, protect and fulfill the right to health and, therefore 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 and, more crucial, to implement forms of reparation in the event of rights violations perpetrated by other parties in addition to the States.

Impact on remedying policy incoherence

8. 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). Nevertheless, in 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).

9. One important aspect is the decisive role of companies in the globalized world. 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.

10. The economic power translates into political power. Powerful companies, especially those monopolists in the market, have an enormous capacity to influence States. 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.

Impact on public health

Systematic human rights violations by pharmaceutical companies

11. Pharmaceutical companies are key actors in the field of development and distribution of medicines and health technologies in the world. They are involved in many crucial decisions: elect disease and target molecules; conduct and/or finance clinical trials; are responsible for quality issues of drugs distributed to the public; pressure and lobby States, multilateral organizations, health professionals in domestic and international level; file for registration of medicines according to their discretion; set high selling prices; among other actions with direct impact on human rights and public health.

12. 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 category of gravity should be subject of tools at its height, being unacceptable that they remain in the field of voluntariness, as discussed below.

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

13. 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. This system directly affects the definition of priorities in R&D, given that it is a clearly a market-driven system.

14. 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.

15. A recent example of lack of prioritization of health needs is the diseases transmitted by the Aedes Aegypti mosquito, especially dengue fever and zika[1]. 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.

16. 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 antiretroviral 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). For those co-infected with Hepatitis C, 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.

17. The extensively documented high prices charged because of patents allows monopolistic practices. The Trade-Related Aspects of Intellectual Property Rights 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. The TRIPS Agreement got in history as one of the most

[1] 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.

controversial components of the of the 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.

18. 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. 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).

19. 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).

20. 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 distributed 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).

21. 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

22. 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".

23. 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 it to undertake the risks of developing the drug, but not to benefit from it (14).

24. 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).

25. Many obstacles are placed to the scope of an appeal in case of rights violations by companies, especially, including:

    1) States have a duty to protect its people from abuse by companies. The language in the Guiding Principles of John Ruggie and incorporated by the IACHR has called it 'Due Diligence'. However, non-state entities are often more powerful than States. Moreover, on several occasions companies and states violate conjugated and accomplice way, being a longa manus one another.

2) Lack of clarity about who violates and who responds, large companies operate regularly through subsidiaries, sub-contractors, contracting chains, associations, cooperatives, conglomerated companies, etc.

3) 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.

Implementation

26. 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.

27. We urge the Intergovernmental Working Group for the Treaty on TNCs and other businesses in the context of Human Rights to adopt the following recommendations (15):

    1) To 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;

    2) That the treaty contains, among other points: the obligation of countries where companies have their headquarters to prevent the adoption of double standard regarding respect for human rights;

    3) 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;

• Section 3: Reference and bibliography

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