

**3rd cycle of Brazil | Universal Periodic Review of the UNHCHR
Shadow Report submitted jointly by the coalition of NGOs of the Working Group of Intellectual
Property of the Brazilian Network for Integration of Peoples**

Identification of organizations

The Working Group of Intellectual Property (Grupo de Trabalho sobre Propriedade Intelectual - GTPI - acronym in Portuguese) is a coalition of civil society organizations created in 2001, coordinated by the Brazilian Interdisciplinary AIDS Association (ABIA – acronym in Portuguese). GTPI conducts studies and advocacy actions to overcome the negative impact of pharmaceutical patents and other monopolistic mechanisms on the access to medicines and on the implementation of health policies in Brazil. The coalition is composed by the following organizations from the Brazilian civil society:

1. ABIA – Associação Brasileira Interdisciplinar de AIDS (Brazilian Interdisciplinary AIDS Association); www.abiaids.org.br
2. Conectas Direitos Humanos (Conectas Human Rights); www.conectas.org
3. FENAFAR – Federação Nacional dos Farmacêuticos (National Federation of Pharmacists); <http://www.fenafar.org.br>
4. Fórum das ONG-AIDS do Estado do Maranhão;
5. Fórum das ONG-AIDS do Estado de São Paulo; www.forumaidssp.org.br/home
6. Fórum das ONG-AIDS do Estado do Rio Grande do Sul; www.forumaidrs.org.br
7. GAPA/SP – Grupo de Apoio à Prevenção à AIDS de São Paulo (Support Group for AIDS Prevention in São Paulo); <http://www.gapabrsp.org.br/>
8. GAPA/RS – Grupo de Apoio à Prevenção à AIDS do Rio Grande do Sul (Support Group for AIDS Prevention in Rio Grande do Sul)
9. GAPA/BA - Grupo de Apoio à Prevenção à AIDS da Bahia (Support Group for AIDS Prevention in Bahia)
10. Gestos – Soropositividade, Comunicação e Gênero (GESTOS - HIV+, Communication and Gender); <http://www.gestospe.org.br/web/gestos/>
11. GIV – Grupo de Incentivo à Vida (Incentive to Life Group); <http://www.giv.org.br>
12. Grupo Pela Vida/SP (Group for Life in São Paulo); <http://www.aids.org.br/>
13. Grupo Pela Vida/RJ (Group for Life in Rio de Janeiro); <http://www.pelavidda.org.br>
14. GRAB – Grupo de Resistência Asa Branca (Resistance Group Asa Branca); <http://www.grab.org.br/>
15. IDEC – Instituto Brasileiro de Defesa do Consumidor (Brazilian Institute for Consumers Protection); <http://www.idec.org.br/>
16. RNP+/MA - Network of People Living with HIV/AIDS Maranhão; <http://rnpvha.org.br/site>
17. RNP+/PI - Network of People Living with HIV/AIDS Piauí;
18. UAEM Brasil - Universidades Aliadas por Medicamentos Essenciais (Universities Allied for Essential Medicines Brazil); www.uaem-br.org/

Abstract

Issues addressed. The report addresses issues related to the fulfillment of the right to health in Brazil in the context of intellectual property rules. Among the challenges addressed, there are: (i) unjustifiably high prices of medicines that threatens public health system sustainability and access to medicines, especially newer, less toxic and more effective drugs; (ii) disputes around the reform of the Brazilian Intellectual Property Law; (iii) the lack of full use of TRIPS flexibilities to promote public health, especially compulsory license; (iv) attacks to the implementation of public health measures, such as the participation of health authorities in the analysis of patent applications in the pharmaceutical sector; (v) TRIPS-plus provisions in Brazilian Law, in court cases and in free trade agreement negotiations; and (vi) the insufficient local production of medicines. Regarding the HIV/AIDS epidemic, despite the universal access policy guaranteed by law, (vii) the infection rate has risen, particularly in some vulnerable social groups; (viii) public HIV/AIDS treatment is financially undermined, presenting rates of destocking for some medicines and lacking incorporation of new less-toxic antiretroviral medicines; and (ix) the mortality rate has risen in some regions of the country. Suggested recommendations are highlighted in the end of each section.

Shadow Report

A. Brazil's obligations regarding the right to health and access to medicines

1. Brazil is signatory of several legally enforceable international declarations and conventions that recognize the right to healthⁱ. At the national level, Brazil recognizes in its Federal Constitution the right to health as a fundamental right of all and a duty of the State.
2. Access to medicines is one of the fundamental elements in achieving progressively the full realization of the right to physical and mental healthⁱⁱ. Key issues related to access to medicines must be taken into account such as: sustainable financing, availability and affordability of medicines.
3. Countries that ratified the ICESCR have a duty to prevent unreasonably high prices for access to essential medicines from undermining the right to health. They are also required to take steps to progressively realize the right to health, prohibit retrogressive measures and immediately fulfil their minimum core obligationsⁱⁱⁱ.
4. Brazil has not only voted in favor but has also sponsored several Human Rights Council resolutions^{iv} on access to medicines that stress the primary responsibility of States to ensure access to medicines to all, without discrimination, in particular essential medicines that are affordable, safe, effective, culturally acceptable and of good quality.
5. In previous cycles of its Universal Periodic Review, Brazil made commitments regarding the right to health by accepting recommendations on the right to health. No recommendation regarding the right to access to medicines related to intellectual property, however, has been made so far, making the UPR 3rd cycle a crucial opportunity for States to do so, as it poses a great challenge for the Brazilian universal health system and for access to medicines in Brazil.



B. Intellectual property system and the right to health

6. Intellectual property rules regulate health technologies at the international level since the adoption of the Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS) at the World Trade Organization (WTO) in 1994. The agreement imposed the obligation for its signatory countries to grant patents for all technological fields, including the health sector.

7. Patents give exclusive rights to its holders and enable them to avoid third parties to produce, use, commercialize, sell or import patented inventions. Potential competitors cannot enter in the market making use of the technology developed during the protection period, which is, in the case of patents for inventions, a 20-year period. Patents limit competition and create a monopolistic situation, enabling patent holders to charge high prices. Such relation has been widely recognized as a policy incoherence^v.

8. According to Article 8 of TRIPS, and reaffirmed by the 2001 Doha Declaration on TRIPS and Public Health, WTO Members countries may adopt necessary measures to protect public health and promote public interest in key sectors to their socioeconomic and technological development. These measures are known as TRIPS flexibilities. Among these provisions, there are compulsory licensing, parallel importation, research exemption and other exceptions to patentability, as well as adopting and applying rigorous definitions of patentability criteria and rigorous patent examination mechanisms to avoid the grant of unmerited patents.

9. However, some countries have pushed for the adoption of more strict standards of protection through provisions not included in TRIPS, known as TRIPS-plus provisions. They are generally harmful to the public interest and, particularly, to the right to health^{vi}. Normally, these stricter provisions are adopted through free trade agreements negotiated with developed countries, but can be also adopted internally by countries. TRIPS-plus provisions includes, among others, test data exclusivity periods, patent for new uses of a known product, patent term extensions.

10. Any intellectual property regime that makes it more difficult for a State party to comply with its core obligations in relation to health is inconsistent with the legally binding obligations of the State party^{vii}. While intellectual property rights may be allocated, limited in time and scope, traded, amended and even forfeited, human rights are timeless expressions of fundamental entitlements of the human person. In addition, the intellectual property regimes primarily protect business and corporate interests and investments^{viii}.

11. States have the duty to protect the rights of their citizens by using TRIPS flexibilities and not assuming TRIPS-plus commitments^{ix}. The UN Special Rapporteur on the Right to Health has recommended that developing countries should include in their national legislation all TRIPS flexibilities to promote access to medicines, as well as removing all TRIPS-plus measures^x. In addition, several resolutions^{xi} adopted by the UN Human Rights Council reiterate the right to the full use of TRIPS flexibilities, as well as the obligation to adopt all available measures to protect the right to health^{xii}.



12. The UN Special Rapporteurship on the Right to Health and the Special Representative of the Secretary-General of the United Nations on the issue of human rights and transnational corporations have stated that the duty to protect the right to health requires a State to ensure that third parties do not obstruct the enjoyment of the right to health^{xiii}.

13. The Global Commission on HIV and Law, in its 2012 Report^{xiv}, recommended categorically the suspension of TRIPS as it relates to essential pharmaceutical products for low and middle income countries and that, in the interim, TRIPS flexibilities should be fully implemented.

14. The recently convened High Level Panel on Access to Medicines^{xv} recommended “*WTO members should commit themselves, at the highest political levels, to respect the letter and the spirit of the Doha Declaration on TRIPS and Public Health, refraining from any action that will limit their implementations and use to promote access to health technologies*”^{xvi}.

C. Issues of access to medicines and intellectual property in Brazil

a. Economic affordability of medicines

15. Until the adoption of TRIPS, Brazil had not adopted the grant of patents to the pharmaceutical sector, such as many other countries, which made it possible to establish the local production of generic medicines at low cost and adopt public policies of universal access to medicines.

16. Brazil approved its current Industrial Property (IP) Law No. 9279 in 1996, which came into force in May 1997, without taking advantage of the 10-year transition period granted by the WTO for developing countries to adapt its national legislations on patents to TRIPS provisions.

17. The change in the IP Law had a great impact in the generic production of medicines in Brazil, overhauling the existing legal regime that permitted local production of medicines at affordable prices. During the 1990s, 1,700 national industrial units producing pharmaceutical intermediates were closed^{xvii}.

18. Prices of medicines are growing exorbitantly in Brazil and constitute a serious threat to the sustainability of Brazilian universal public health system. The public budget for health in 2015 corresponded to 4,29% of the 2,38 trillion reais of the Union Budget^{xviii}. Figure 1 represents the Evolution of the Ministry of Health’s spending with medicines, in reais, from 2003 to 2014, indicating a growth of 650%.



Figure 1. Evolution of the Ministry of Health's spending with medicines.
Source: National Health Fund and CGPLAN/SCTIEMS. Updated: Feb. 2014.

19. The expenditure with antiretroviral medicines only corresponded to 10,78% of the Ministry of Health's budget^{xix}. The Ministry of Health has recognized that the increase in prices of medicines has put in risk the sustainability of the policy of universal access to HIV/AIDS medicines for all in need in the country^{xx}.

20. The current scenario of economic crisis and political instability do not bring optimistic perspectives to the future of public health in Brazil. In fact, the recently established government, not referenced by popular democratic vote, has given very worrying declarations and proposals in this sense. The recently appointed Ministry of Health and the President have publicly expressed the government's position of shrinking the Public Health System^{xxi}. Currently, there is a Law being discussed in congress to freeze public expenditure with health and education for the next 20 years^{xxii}.

21. In recent years there has been a global trend of increased costs to the health care systems due, among other factors, by increases in the price of medicines. This trend may be related to several factors, one of the largest impact on budgets to incorporate new technologies, protected by intellectual property system and sold at high prices in a monopoly situation.

22. Generic competition could be a very effective way to lower medicine prices in a sustainable way, however patents are an impediment, keeping prices high. The full use of TRIPS flexibilities constitutes, in this context, not only a right but a duty of the Brazilian State to promote and fulfill the human right to health of its population. However, there are many measures that need to be adopted by Brazil in order to face the challenges posed by intellectual property to access to medicines.

b. Brazilian Intellectual Property Legislation

23. Brazilian IP Law (9.279-96) did not fully incorporated the public health flexibilities allowed by TRIPS and went beyond the commitments required by TRIPS by adopting TRIPS-plus measures. The reform of the patent law, with the exclusion of TRIPS-plus measures and full adoption of



measures to protect public health, can increase the possibilities of purchasing more affordable generic medicines, increasing access for the population and saving public resources that can be used to improve the health system as a whole.

24. In 2012, GTPI conducted a study about the Brazilian IP law from the perspective of the human right to health. The study concluded that out of 11 measures regularly adopted by countries for the protection of public health (known as “flexibilities” or “safeguards”), Brazilian IP law had adopted 6 measures (participation of health authorities in patent application examination, interpretation of patentability criteria according to national standards, exceptions to patentability, Bolar exemption, experimental use, compulsory license), had restrictively adopted 3 measures (parallel importation, patent opposition and public non-commercial use), and did not adopt 2 measures (compulsory license for export under paragraph 6 and transition period).

25. On the other hand, the Brazilian legislation did adopt measures that are detrimental to public health which do not derive from obligations assumed by TRIPS (known as “TRIPS-plus”). The study identified 3 TRIPS-plus provisions that were adopted by the Brazilian legislation (“pipeline” revalidation patents, patent term extension and test data exclusivity for veterinarian use) and 2 others (patents for new uses and new forms of known products) that, despite not having been adopted by the legislation, were incorporated through administrative norms of the Brazilian patent office, the National Institute of Industrial Property (INPI, as per the acronym in Portuguese), and could be avoided by changes in the legislation.

26. A number of law bills seeking to amend the IP Law are currently under analyses by Brazilian Congress. Some of them aim to include or improve the provisions related to public health flexibilities and other aim to adopt TRIPS-plus measures. The analysis of the bills can be found in Annex II.

27. ***Recommendation. Brazil should review its national Industrial Property law to fully incorporate TRIPS flexibilities and to exclude TRIPS-plus measures, in order to promote the human right to health.***

c. Use of TRIPS flexibilities

28. The Brazilian IP law already contains some TRIPS flexibilities that could be used more often and more effectively to promote the human right to health.

i. Compulsory License

29. Evidence shows the positive impact of issuing compulsory licenses (CL) both in terms of enhancing access to medicines and obtaining expressive savings for public budget.

30. However, Brazil has issued compulsory license only once in 2007: for efavirenz, a medicine used to treat HIV/AIDS. The total savings in the purchase of generic efavirenz in a five year period (2007-2011) after the compulsory license was issued was around US\$ 104 million, allowing for the increase in the number of people on treatment with efavirenz from 70,000 in 2007 to 100,000 in 2011^{xxiii}.



31. Apart from the one time that the Brazilian government issued a compulsory license, the mere possibility of issuing compulsory licenses has been an important strategy employed by the Brazilian government to pressure pharmaceutical companies in price negotiations for ARV and other medications. However, since the country has almost never issued compulsory licenses except once, such strategy grew increasingly less effective and the prices agreed in later rounds were unsatisfactory^{xxiv}.

32. ***Recommendation: Brazil should strengthen the full use of TRIPS flexibilities in order to enhance access to medicines and promote the human right to health, including by issuing compulsory licences for medicines for public interest.***

ii. Public health protection mechanism at pharmaceutical patent request examination

33. Public health protective measures are not only those that ensures the generic competition to achieve more affordable prices during the patent term, such as compulsory license, but also the establishment of rigorous public health-sensitive patentability and innovation criteria that curtails the evergreening of patents and awards patents only when genuine innovation has occurred.

34. Since 2001, the grant of a patent in the pharmaceutical area in Brazil depends by law^{xxv} on the prior consent of the National Agency for Sanitary Vigilance (ANVISA) – the Brazilian drug regulatory authority. Such legislation determines that ANVISA should work in partnership with National Institute of Industrial Property (INPI) – the Brazilian patent office. ANVISA's prior consent represents the participation of Ministry of Health officials in the processes of analyzing pharmaceutical patent applications.

35. The World Health Organization identified that a close collaboration between health regulatory authorities and patent offices in the examination of pharmaceutical patent applications enhances the examination of pharmaceutical patents from a public health perspective^{xxvi}. In this sense, ANVISA's prior consent has been considered an innovative and exemplary practice in the public health protection, recognized by the WHO as positive since it helps to prevent concession of unmerited patents^{xxvii}.

36. Evidence^{xxviii} shows that ANVISA's participation on the analyzes of pharmaceutical patent applications, in addition to preventing the granting of numerous undeserved patents, also corrected dozens of inaccuracies in applications that in INPI's view would be ready for approval, reducing or clarifying the scope of the object protected by the patent. Therefore, ANVISA's participation in the examination also increases the quality of the patents that are granted.

37. The UN Working Group on Business and Human Rights, in its report regarding the visit to Brazil in 2015, emphasized^{xxix} that without ANVISA's involvement, there was a higher risk of patent monopolies emerging, which would hinder access to medicines.

38. However, there are many attempts to limit ANVISA's prior consent on the analysis of pharmaceutical patent examination by different actors, such as the INPI itself, pharmaceutical companies and even other countries^{xxx}.

39. ***Recommendation: Brazil should strengthen the full use of TRIPS flexibilities in order to enhance access to medicines and promote the human right to health, including by keeping into practice the mandatory participation of health authorities in the patent application examination process in the pharmaceutical sector, known as the Anvisa's prior consent mechanism.***

iii. Local production of medicines

40. States have an immediate obligation to take legal and administrative measures to ensure that access to essential medicines for their populations is secured by all available means^{xxxi}. One very important mean is the local production of medicines.

41. In the 1990's, public-owned laboratories played a strategic role that was key to ensuring that a policy of universal access to ARVs could be a reality, both by producing off-patent medicines and by establishing a possible price of production that was used as reference in price negotiations for patented medicines. However, they have progressively lost this role.

42. Public-owned laboratories could make further use of TRIPS flexibilities, such as Bolar exemption, to start to produce strategic medicines used in the public health system. The use of Bolar exemption would assure that the generic version of the medicine can be commercialized as soon as the patent expires, or could provide the government with the option of issuing a compulsory license without the need to import the generic version from other countries while the local production is underway.

43. This is an urgent matter in face of the increasing number of voluntary licenses being signed by patent holders and generic producers of other countries, especially India, limiting the geographical scope of countries that can have access to the generic medicines produced, from which Brazil is excluded. Since the active pharmaceutical ingredient (API) is usually an expensive part in the production of a medicine, Brazilian public laboratories could also start the production of APIs, instead of negotiating licenses that will transfer the technology of API production only to private laboratories.

44. ***Recommendation: Brazil should strengthen the full use of TRIPS flexibilities in order to enhance access to medicines and promote the human right to health, including by using measures that allow for the local production of priority medicines (both finish product and active pharmaceutical ingredient), preferably by public-owned laboratories.***

d. TRIPS-plus measures

i. Revalidation "pipeline" patents

45. One example of TRIPS-plus measure adopted by Brazilian IP law is the "pipeline patents" (articles 230 and 231), a revalidation of patents granted abroad before patents for

pharmaceuticals products were granted in Brazil. In total, 1,182 patent applications were filed through the pipeline mechanism^{xxxii}. This represented at least 340 medicines that were patented in Brazil that would not have been if the pipeline mechanism were not adopted. TRIPS did not require that countries grant this kind of retroactive patents. A similar provision was proposed during the negotiations but was rejected.

46. A study conducted by the Institute of Economy of the Federal University of Rio de Janeiro estimated the losses caused by the adoption of the pipeline mechanism in Brazil in the case of government purchases of five ARV medications from 2001 to 2007. The data revealed that Brazil spent between US\$420 million and US\$519 million more buying these 5 ARVs during this period from the patent holders than it would have spent if it could have bought the generic versions of the medicines available at the international market^{xxxiii}.

47. GPI members organizations petitioned the Brazilian Prosecutor General requesting the questioning of the constitutionality of the patents issued under the pipeline mechanism to the Brazilian Supreme Court, culminating in the filing of a Direct Action on Unconstitutionality nº. 4234, which is currently being judged^{xxxiv}.

48. ***Recommendation. Brazil should consider revoking all TRIPS-plus measures adopted in the country, including the annulment of all patents granted through the “pipeline mechanism”.***

ii. Extension of the patent term

49. The Brazilian IP law (sole paragraph of the article 40) allows the extension of the patent term when there is a delay in the granting of the patent, going beyond the period of 20 years established by TRIPS.

50. A recently published study conducted by the Institute of Economy of the Federal University of Rio de Janeiro, estimated the losses caused by the provision that allows the patent term to be extended. The study included the government purchase of 9 medicines which patents were subject to extension. The data showed that Brazil spent an average of R\$ 933 millions more per year of extension, buying these 9 medicines from the patent holders than it would have if it could have bought generic versions of the medicines^{xxxv}.

51. ***Recommendation. Brazil should revoke all TRIPS-plus measures adopted in the country, including the annulment of all patents term extensions granted beyond the 20 years period as determined by TRIPS.***

iii. Test data exclusivity

52. In Brazil, Law 10.603/02 regulates information regarding pharmaceutical products for veterinary use, fertilizer and pesticides, determining an exclusivity period of 10 years for data related to products which use new chemical and biological entities. This law does not apply to pharmaceutical products for human use. Law 9.279/96 (IP law) classifies as an anti-competitive crime the unfair disclosure or unauthorized use of the data (article 195, XIV). This provision in the IP law provides protection against unfair commercial use, but does not grant exclusive rights over

the data, being, therefore, TRIPS-compliant.

53. However, some pharmaceutical companies are filing lawsuits requiring data exclusivity to be granted also for medicines for human use and those requests are being granted by the Judiciary system, preventing registration of generic medicines.

54. Data exclusivity is a way to delay the market entrance of generic drugs, which allows for a private monopoly even when there is no patent protection. Monopolies - such as patents and data exclusivity - limit competition and create access barriers, which, in turn, limit purchase options and help to maintain high prices. Data exclusivity gives additional protection to producers of innovator drugs at the expense of access to quality medicines at affordable prices and the ethics of research in humans.

55. ***Recommendation. Brazil should revoke all TRIPS-plus measures adopted in the country, including the annulment of all test data exclusivity for medicines for human use already granted, as well as take the necessary measures to avoid the grant of new test data exclusivity.***

iv. Free trade agreements - European Union and Mercosur

56. A free trade agreement is under negotiation between the European Union and Mercosur countries, including a chapter with IP provisions. It constitutes a subject of concern in terms of the negative impact for the access to medicines for Mercosur countries. EU's position in negotiations of FTAs includes introducing TRIPS-plus provisions, exerting pressure on countries to prevent the use of TRIPS public health safeguards and flexibilities to reduce medicine prices and using technical assistance programmes to further export excessive IP standards^{xxxvi}. However, States parties of the ICESCR should ensure that international agreements do not adversely impact upon the right to health^{xxxvii}.

57. The UN High Level Panel on Access to Medicines recommended that governments engaged in bilateral or regional trade or investment treaties should systematically conduct health impact assessments, in order to verify if they endanger human rights and public health, as well as conduct negotiations transparently and publicly available^{xxxviii}.

58. ***Recommendation: Brazil should abstain from adopting TRIPS-plus provisions and should conduct health impact assessments of any trade agreement in negotiation, as well as conduct negotiations transparently and publicly available, ensuring that international trade and investment agreements, such as the EU-Mercosur FTA, actively improve instead of hinder the right to access to medicines and the right to health of its populations.***

e. Alternative mechanisms to promote health innovation

59. Evidence shows that the current research and development (R&D) system based on IP protection does not lead to greater innovation and affordable prices. The imbalances in the current R&D system were the subject of the 2012 report of the WHO's Consultative Expert Working Group on Research and Development (CEWG)^{xxxix}. The CEWG recommended a global binding agreement that provides a needs-driven framework for R&D, guided by the core principles of affordability, effectiveness, efficiency, and equity, and grounded in the concepts of de-linkage

and knowledge-sharing approaches. The recent report by the UN Secretary-General's High-Level Panel on Access To Medicines has restated the need for negotiating a binding convention and calls on governments to take action^{xi}.

60. *Recommendation. Brazil should reinforce its prominent role in the promotion of the right to health, including by actively financing pilot projects and engaging on negotiations for an binding convention of alternatives models of research and development for new health technologies, such as recommended by the WHO Consultative Expert Working Group report and the UN High Level Panel on Access to Medicines report.*

f. Pharmaceutical companies

61. Currently, there has been concrete actions carried out by pharmaceutical companies, both transnational and national, that directly affect the access to medicines by the Brazilian population.

62. Pharmaceutical companies, in order to avoid the effective patent law from a right to health perspective, carry out intense lobby in Brazilian Legislative. Lobby in Brazil is not regulated and the pharmaceutical companies activities are not conducted with transparency.

63. In Judiciary, pharmaceutical companies questions the legitimate use of TRIPS flexibilities, such as the participation of Ministry of Health officials in the analyses of pharmaceutical patent applications (ANVISA's prior consent). Companies also seek the application of TRIPS-plus measures not provided for in Brazilian patent law, such as data exclusivity.

64. According to the Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines^{xii} elaborated by UN Special Rapporteurship on the Right to Health, pharmaceutical companies should not seek to limit, diminish or compromise the 'flexibilities' and other features of the intellectual property regime that are designed to protect and promote access to existing medicines.

65. It is of particular concern the Collective Action filed in November 2014 by Pharmaceutical Research Industry Association^{xiii} (INTERFAMA - acronym in Portuguese), an association of 52 pharmaceutical companies, mostly transnational, responsible for the majority of reference drugs sales in Brazil. INTERFARMA's Collective Action directly questions the legality of ANVISA's prior consent mechanism mentioned previously.

66. It is important to emphasize that the improper keeping of an Attorney General Office's (AGU) legal opinion has been serving as basis for institutional disputes that put in hazard the role of the health sector in the patent granting process, including INTERFARMA's Collective Action. This has been subject of one urgent appeal sent to the Special Rapporteurship on the Right to Health, which Brazil has never replied.

67. The violations committed by the pharmaceutical companies of not complying with Brazilian public health provisions in the IP Law require further regulation. In this sense, it is essential the engagement of the Brazilian government in the development of an international legally binding instrument that would hold companies accountable for human rights violations.



68. ***Recommendation: Brazil should continue to protect public health safeguards that prevent the negative impact of patents on the right to health, including by preventing third parties, such as the private sector, from weakening established institutional and normative framework aimed at enhancing access to medicines, and should actively engage in the negotiations of a binding treaty for human rights violations committed by companies ongoing at the United Nations, such as the Intergovernmental Group on Human Rights and Transnational Corporations.***

D. The HIV/AIDS Epidemic in Brazil

69. Since the beginning of the HIV/AIDS epidemic in Brazil in 1980, up to June 2015, 798,366 AIDS cases were registered in the country. From 2010 to 2015, Brazil registered a yearly average of 40,600 AIDS cases^{xliii}.

70. Brazil was the first developing country and one of the few countries in the world to offer universal and free access policy of treatment for people living with HIV/AIDS. The policy of universal access to antiretroviral treatment in Brazil has produced important results. From 1997 to 2004, there was a 40% reduction in mortality and a 70% reduction in morbidity as a direct consequence of highly active antiretroviral therapy. From 1993 to 2003, the average life expectancy for AIDS patients increased by nearly five years, reflecting a significant increase in quality of treatment. Furthermore, there was a reduction of 80% in hospitalizations, saving US\$2.3 billion.

71. Access to proper ARV treatment over the past years has substantially transformed the lives of people and the methods of controlling HIV infection, improving quality of life for people living with HIV-AIDS, increasing their life expectancy, reducing the transmissibility of the virus and causing a significant decline in mortality rates. The Brazilian program establishes the importance of ensuring universal access to treatment for all who need it^{xliiv}.

72. According to the Ministry of Health, by the end of 2014, the prevalence rate of HIV among Brazilian population was of 0.39%. Among them, 83% (649,000) had been diagnosed. Approximately 80% of these have been under a health service at some point after diagnosis; however, only 66% remained under treatment in these services. In addition, 52% (405,000) of the people living with HIV/AIDS were in antiretroviral therapy, and 46% (356,000) of them had viral suppression at least six months after the start of treatment. Considering only PLWH on ART, the proportion of viral suppression reaches approximately 88%^{xliv}.

73. It is important to emphasize that the 90-90-90 goal does not take into account important aspects of the situation of HIV/AIDS. Among them, there are the dimensions of the quality of the treatment and obstacles to access to treatment caused mainly by unjustifiably high prices of antiretroviral drugs. The 90-90-90 could create, additionally, the risk of standing out over the necessary goal of leaving no one behind in the fight against AIDS. It is also necessary to give the same attention on goals on reducing stigma and discrimination as well prevention to avoid new HIV transmission, so it would not constitute a late and underlying aspect.

74. The Brazilian government adopted the "Clinical Protocol and Therapeutic Guidelines for the Management of HIV Infection in Adults" (PCDT), in December 2013, recommending the immediate start of ART for all PLWH, regardless of CD4 count. Evidence shows that the approach of initiating treatment earlier contributes to reduce the risk of development of the disease^{xlvi} and the ART is an efficacious way to reduce HIV transmission^{xlvii}.

75. However, several challenges remain. About 130,000 people infected with HIV in Brazil do not know their diagnosis. Moreover, despite the reduction observed in the treatment gap in recent years, almost one third of people living with HIV/AIDS associated to a public health service continues without antiretroviral therapy^{xlviii}.

76. In addition, AIDS growth, particularly in youth (15-24 years), remains a major concern and shows that the actions in this segment have to be intensified. UN Committee on Economic, Social and Cultural Rights has shown concern regarding the growing number of HIV/AIDS cases registered during the last decade, noting with apprehension that, although treatment with antiretroviral drug therapy is available for free, the prevalence of HIV/AIDS is still high, particularly among economically disadvantaged communities^{xlix}. The 2014 UNAIDS report indicates that new HIV infections increased by 11% between 2005 and 2013 in Brazil. Only in 2013, the country registered 47% of all new cases recorded in Latin America.^l

77. One important aspect of the Brazilian epidemic is that although the number of cases in males is higher among heterosexuals, most new cases of HIV in the country has been concentrated in key populations, particularly gay men and men who have sex with men, as well as transvestites and transsexuals, people who use drugs and sex workers^{li}.

78. From the beginning of the AIDS epidemic up to December 2014, 290,929 deaths caused by AIDS were identified. Although the standardized AIDS mortality rate fell in 5% in the last decade for Brazil, going from 6.0 deaths per 100,000 inhabitants in 2005 to 5.7 in 2014, it did not reduce in all regions of the country. Only the Southeast and South regions show declining trends: in the South, it fell by 10.6% and in the Southeast, the reduction was more pronounced: 19.7%. In the North and Northeast regions, AIDS mortality rate grew in the last ten years; in the North, the coefficient increased by 58.6%, moving from 4.6 deaths per 100,000 inhabitants in 2005 to 7.3 in 2014, and in the Northeast, increased 34.3%, going up from 3.2 to 4.3 deaths per 100,000 inhabitants. The Midwest region remained the coefficient of 4.5 in 2005 and 2014^{lii}.

79. ***Recommendation: Brazil should undertake significantly efforts to tackle HIV/AIDS epidemic by reducing sharply both the infection rate, particularly in most vulnerable social groups, and the mortality rate, particularly in the poorest regions of the country, as well as effectively guarantee universal treatment with medicines that are safe, effective, of good quality and with medical protocols periodically reviewed.***



Annex I

Evaluation of recommendations made to Brazil in previous cycles regarding the right to health

Recommendation received	No.	Made by	Evaluation of implementation	Suggestions of new recommendations
Improve health-care efforts, especially to reduce child mortality and the prevalence rate of HIV and AIDS	A/HRC/21/11, par. 119.152	Iran	Unsatisfactory implementation (regarding HIV/AIDS). The prevalence rate of HIV/AIDS has risen in some regions of the country.	Brazil should undertake significantly efforts to tackle HIV/AIDS epidemic by reducing sharply both the infection rate, particularly in most vulnerable social groups, and the mortality rate, particularly in the poorest regions of the country, as well as effectively guarantee universal treatment with medicines that are safe, effective, of good quality and with medical protocols periodically reviewed.
Continue its efforts to guarantee free and quality health services	A/HRC/21/11, par. 119.148	Cuba	Unsatisfactory implementation with threats of setbacks. Recently announced health policy changes signalize a major weakening of the public health system and its universality and integrality.	Brazil should strengthen the constitutional principles of universality and integrality of its public health system, including by guaranteeing integrally free health services of quality and fulfilling its obligation of prohibiting retrogressive measures in the right to health.
Take more effective measures to address the problem of social and economic inequality, in particular in the areas of health, education and employment opportunities between the population in the urban and rural areas	A/HRC/21/11, par. 119.154	Malasia	Unsatisfactory implementation (regarding health inequities). Brazilian population still face major gaps in health inequalities, particularly between regions and within cities, and also worse health indicators among black and indigenous people.	Brazil should undertake significantly efforts to reduce sharply its health inequalities, by adopting health policies that aims to benefit primarily those who lack access to a quality public health service, such as indigenous and black people, particularly Quilombola's communities, as well as reduce the gap between regions, giving particular attention to North and Northeast regions, as well as people spacially segregated within Brazilian cities.

Annex II

Analysis of bills of law currently being discussed at Brazilian Congress to amend IP Law (9276/96)

BILL OF LAW	AUTHOR	SUMMARY
139/1999	Alberto Goldman - PSDB/SP	It has two objectives: i) to change the rights of exhaust system, to allow parallel imports of products marketed by the proprietor or with authorization, and ii) to allow the issuance of the compulsory license when the patent object is not exploited in Brazil, regardless of the economic viability of the exploration.
3562/2000	Raimundo Gomes de Matos - PSDB/CE	It aims to include new hypothesis of compulsory licensing for medicines in case of incomplete or exploration when the price is incompatible with the cost of production.
303/2003	Dr. Pinotti - PMDB/SP	It establishes the possibility of compulsory license issuance in case of not manufacturing of patent object in Brazil, removing the exception of economic infeasibility.
22/2003	Roberto Gouveia - PT/SP	It aims to include ARV medicines on the list of subject matter not entitled to patent protection in Brazil. The bill is in full compliance with the underlying principles of the Brazilian Constitution and international human rights law, which gives precedence to the right to health and the right to life over the commercial rights and economic interests of pharmaceutical companies. Furthermore, it also conforms to commercial international regulations on the subject, which, while recognizing industrial property rights, also admits that developing countries like Brazil can and should adopt measures to protect public health and assure access to medicine for everyone in cases of epidemics, such as AIDS.
11/2007	Fernando Coruja - PPS/SC	It aims to make expressly prohibited the grant of patent for medical use of a product already known, preventing the grant of "second use" patent. The bill aims to increase the rigor of the patentability criteria, preventing the granting of undeserved patents.
2511/2007	Fernando Coruja - PPS/SC	It aims to make expressly prohibited the grant of patent for medical use claims of a product already known, preventing the patenting of "second use".
95/2008	Paulo Teixeira - PT/SP Dr. Rosinha - PT/PR	It aims to prevent the grant of patents for new uses of products already known and polymorphs.



3.709/2008	Rafael Guerra - PSDB/MG	It aims to restrict the application of the "prior consent of ANVISA" only to patent applications made by the revalidation mechanism "pipeline". Such a bill can restrict the actions of ANVISA that has been important for the analysis of the patentability requirements for essential medicines for the Unified Health System (SUS) of Brazil.
3709/2008	Rafael Guerra - PSDB/MG	It aims to restrict the application of the "prior consent of ANVISA" only to patent applications made by the "pipeline" revalidation mechanism
5176/2009	Rodrigo Rollemberg - PSB/D	It aims to include new hypothesis of compulsory licensing for medicines, explaining their use in case of lack of continued use of medicines in the market
689/2011	Il do Rêgo - PMDB/PB	It aims to repeal the sole paragraph of the Article 40 of Law 9.279 / 96 which allows the extension of the patents period of validity in case of delay in the analysis by the National Institute of Industrial Property (INPI).
3.943/2012	Jandira Feghali - PCdoB/RJ José Linhares - PP/CE Elcione Barbalho - PMDB/PA and others	It aims to regulate the ANVISA's prior consent in the analyzing of the pharmaceutical patent applications, proposing changes in Article 229-C of Law 9,279 / 96 to expressly include in ANVISA's institutional capacity the prerogative to analyze the patentability requirements.
4/2012	Jandira Feghali - PCdoB/RJ José Linhares - PP/CE Elcione Barbalho - PMDB/PA and others	It aims to repeal the extension of the patents period of validity in case of delay in the grant by the National Institute of Industrial Property (INPI), from the exclusion of the Article 40, sole paragraph of Law 9,279 / 96. The current wording of the Article 40 goes against the social interest because it extends a harmful monopoly not only to the competition, but also to the capacity of the brazilian Unified Health System (SUS) and individual consumers to bear the costs of the medicines.
2/2013	Arilton Lima - PT/SP Dr. Rosinha - PT/PR	The bill proposes a number of changes in the law to: <ul style="list-style-type: none"> - Repeal the possibility of extension of the patent for the delay in granting the INPI; - Adding objects that are not inventions, especially with regard to new uses and new forms of known products; - Change the accuracy of the patentability criteria related to the inventive activity; - Create the opposition mechanism against patent applications; - Modify the legal provision on the ANVISA's prior consent, in order to provide that it should examine the object of the patent application in the light of public health, considered contrary to public health applications that present health risks or do not comply with requirements of patentability; - Establish the mechanism of public non-commercial use of the patent object or patent applications, without the consent or authorization of the proprietor, for purposes of public interest, including national defense and social interest.



3994/2012	Jandira Feghali - PCdoB/RJ; José Linhares - PP/CE; Elcione Barbalho - PMDB/PA e outros	It repeal the extension of the term of invention patents in case of delay in the grant by the National Institute of Industrial Property (INPI), from the exclusion of art. 40, sole paragraph of Law 9279 / 96.
3945/2012	Jandira Feghali - PCdoB/RJ; José Linhares - PP/CE; Elcione Barbalho - PMDB/PA outros	It aims to not grant patents to products for the treatment and diagnosis of neglected diseases and non-payment of royalties in the event of a compulsory license issue.
8090/2014	Comissão de Seguridade Social e Família	It aims to allow the issuance of compulsory license by a country that can produce medicines to another country that does not have capacity to produce the medicine object of the license.
8091/2014	Comissão de Seguridade Social e Família	It aims to replace the internal mode of the intellectual property rights exhaust for the international mode, allowing the importation of the patented product, and also the importation of not traded products directly by the patentee or his licensee

ⁱ Universal Declaration of Human Rights (article 25); the International Covenant on Economic, Social and Cultural Rights (article 12); the International Covenant on Civil and Political Rights (article 5); the Declaration of Commitment on HIV/AIDS (articles 58 to 61); and Declaration on the right to development (article 8).

ⁱⁱ UNITED NATIONS GENERAL ASSEMBLY. Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. A/61/338, paragraph 40.

ⁱⁱⁱ UNITED NATIONS. COMMITTEE ON ECONOMIC, SOCIAL AND CULTURAL RIGHTS [CESCR], General Comment n. 17. The right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author (art. 15). par.1 (c). E/C.12/GC/17. Paragraph 35. (2006).

^{iv} UNITED NATIONS. GENERAL ASSEMBLY. HUMAN RIGHTS COUNCIL. A/HRC/RES/12/24, A/HRC/RES/17/14, A/HRC/RES/23/14.

^v UNITED NATIONS. HIGH-LEVEL PANEL ON ACCESS TO MEDICINES.

^{vi} UNITED NATIONS. High Level Panel on Access to Medicines Report. 2016. Page 27.

^{vii} UNITED NATIONS. SUBSTANTIVE ISSUES ARISING IN THE IMPLEMENTATION OF THE INTERNATIONAL COVENANT ON ECONOMIC, SOCIAL AND CULTURAL RIGHTS. Follow-up to the day of general discussion on article 15.1 (c), November 2001. Human rights and intellectual property. Statement by the Committee on Economic Social and Cultural Rights. E/C.12/2001/15. Paragraph 12. 2001.

^{viii} UNITED NATIONS. COMMITTEE ON ECONOMIC, SOCIAL AND CULTURAL RIGHTS [CESCR], General Comment n. 17. The right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author (art. 15). par.1 (c). E/C.12/GC/17. Paragraphs 2 and 3. (2006).

^{ix} UNITED NATIONS. High Level Panel on Access to Medicines Report. 2016. Page 25.



^x UNITED NATIONS. HUMAN RIGHTS COUNCIL. Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. A/HRC/11/12. 2009.

^{xi} UNITED NATIONS. GENERAL ASSEMBLY. HUMAN RIGHTS COUNCIL. A/HRC/RES/12/24, A/HRC/RES/17/14, A/HRC/RES/23/14.

^{xii} UNITED NATIONS. United Nations High Commissioner for Human Rights. Intellectual property rights and human rights. Sub-Commission on Human Rights Resolution 2000/7. Paragraph 5. (2000).

^{xiii} UNITED NATIONS. HUMAN RIGHTS COUNCIL. Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health on access to medicines. A/HRC/23/42. 2013; and Ruggie, J. (2009) Report of the Special Representative of the Secretary-General of the United Nations on the issue of human rights and transnational corporations and other business enterprises, a/hrc/11/13/aDD.1. Available at:

<https://documents-dds-ny.un.org/doc/UNDOC/GEN/G09/133/98/pdf/G0913398.pdf?OpenElement>.

^{xiv} "While the Commission recommends that WTO Members must urgently suspend TRIPS as it relates to essential pharmaceutical products for low and middle income countries, we recognize that such change will not happen overnight. In the interim, even though individual countries may find it difficult to act in the face of political pressure, they should, to the extent possible, incorporate and use TRIPS flexibilities, consistent with safeguards in their own national laws." Global Commission on HIV and Law 2012 Report. Available at:

<http://www.hivlawcommission.org/resources/report/FinalReport-Risks,Rights&Health-EN.pdf>.

^{xv} More information on the High Level Panel available at: <http://www.unsgaccessmeds.org/>.

^{xvi} UNITED NATIONS. High Level Panel on Access to Medicines Report. 2016. Page 9.

^{xvii} ORSI, F., HASENCLEVER, L., FIALHO, B., TIGRE, P., CORIAT, B. Intellectual Property Rights, Anti-AIDS Policy and Generic Drugs, ANRS, 2003.

^{xviii} Information obtained through Access to Information Law.

^{xix} Information obtained through Access to Information Law.

^{xx} The Sustainability of the Universal Access to Antiretroviral Drugs in Brazil. Ministry of Health. Brasília, 2005.

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^{xxi} Size of the Brazilian Public Health System needs to be revised, said new Minister of Health, 2016. Available in Portuguese at: <http://www1.folha.uol.com.br/cotidiano/2016/05/1771901-tamanho-do-sus-precisa-ser-revisto-diz-novo-ministro-da-saude.shtml>

^{xxii} Brazilian Chamber of Deputies approves bill limiting public spending for 20 years, 2016. Available in Portuguese at: <http://agenciabrasil.ebc.com.br/politica/noticia/2016-08/ccj-da-camara-aprova-pec-que-limita-gastos-publicos-por-20-anos>

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<http://pag.aids2012.org/session.aspx?s=228#2>.

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http://www.scielo.br/pdf/rsp/v40s0/en_09.pdf.

^{xxv} Law No. 9.279/1996, Article 229-C: "the grant of patents to pharmaceutical products and processes will depend on the previous approval of the National Health Surveillance Agency - ANVISA." Available at:

http://www.wipo.int/wipolex/en/text.jsp?file_id=12539.

^{xxvi} Guidelines for the examination of pharmaceutical patents: Developing a public health perspective, WHO-ICTSD-UNCTAD, by Carlos Correa, Professor, University of Buenos Aires, January 2007, page 25. Available at:

http://www.ictsd.org/sites/default/files/research/2008/06/correa_patentability20guidelines.p.

^{xxvii} Final Report of the WHO Commission on Intellectual Property Rights, Innovation and Public Health, CIPIH/2006/1, p. 134. Available at:

<http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.p>.



- ^{xxviii} ANVISA. Coordination of Intellectual Property. Technical Note on Problems in Pharmaceutical Patents Applications.
- ^{xxix} UNITED NATIONS. Working Group on the issue of human rights and transnational corporations and other business enterprises. Report on visit to Brazil. A_HRC_32_45_Add.1_AEV. Paragraph 16.
- ^{xxx} For instance, pharmaceutical companies have filed lawsuits questioning the legality of such measure (which is best described further, in the Pharmaceutical Companies section of this report). Moreover, the United States have more than once included ANVISA's prior consent in its Priority Watch List[#] – a list of concerns regarding intellectual property regulation in other countries that can lead to direct or indirect sanctions by the US.
- ^{xxxi} UNITED NATIONS HUMAN RIGHTS COUNCIL. Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover, on access to medicines. A/HRC/23/42. Paragraph 11.
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<http://deolhonaspontentes.org/item/pontentes-pipeline/>
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- ^{xxxv} Available at: <http://deolhonaspontentes.org/wp-content/uploads/2016/09/O-custo-da-extens%C3%A3o-das-pontentes-para-o-SUS-vf.pdf>.
- ^{xxxvi} Oxfam and Health Action International. Joint Agency Briefing Paper. Trading away access to medicines. 2014. Available at: https://www.oxfam.org/sites/www.oxfam.org/files/file_attachments/bp-trading-away-access-medicines-290914-en.pdf.
- ^{xxxvii} UNITED NATIONS. COMMITTEE ON ECONOMIC, SOCIAL AND CULTURAL RIGHTS [CESCR], General Comment n. 14.
- ^{xxxviii} UNITED NATIONS. High Level Panel on Access to Medicines Report. 2016. Pages 9 and 34.
- ^{xxxix} Report of the Consultative Expert Working Group on Research and Development: Financing and Coordination, 2012. Available at: http://www.who.int/phi/CEWG_Report_5_April_2012.pdf?ua=1
- ^{xl} UNITED NATIONS. High Level Panel on Access to Medicines Report. 2016
- ^{xli} United Nations. Special Rapporteurship on the Right to Health. Human Rights Guidelines for Pharmaceutical Companies. Available at:
<http://www.ohchr.org/Documents/Issues/Health/GuidelinesForPharmaceuticalCompanies.doc>.
- ^{xlii} Available at: <http://www.interfarma.org.br/>.
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- ^{xlvi} This article was published on July 20, 2015, at NEJM.org. DOI: 10.1056/NEJMoa1506816 Copyright © 2015 Massachusetts Medical Society.



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