







**Universal Periodic Review of the UN Human Rights Council – BRAZIL**  
**Information submitted by the coalition of NGOs GTPI/Rebrip – Grupo de Trabalho sobre Propriedade**  
**Intelectual da Rede Brasileira pela Integração dos Povos**  
[www.patentes.org.br](http://www.patentes.org.br)

## Human right to health: access to medicine for HIV/AIDS in Brazil

### Identification of the organizations

1. The Working Group of Intellectual Property of the Brazilian Network for the Integration of Peoples (GTPI/Rebrip – acronym in Portuguese) was created in 2001 and is coordinated by the Brazilian Interdisciplinary AIDS Association (ABIA – acronym in Portuguese). It is comprised of the following organizations from the Brazilian civil society:

<p>(1) ABIA – Associação Brasileira Interdisciplinar de AIDS (Brazilian Interdisciplinary AIDS Association);</p> <p><a href="http://www.abiaids.org.br">www.abiaids.org.br</a></p>	 <p>Associação Brasileira Interdisciplinar de AIDS</p>
<p>(2) Conectas Direitos Humanos (Conectas Human Rights);</p> <p><a href="http://www.conectas.org">www.conectas.org</a></p>	 <p>CONECTAS DIREITOS HUMANOS</p>
<p>(3) FENAFAR – Federação Nacional dos Farmacêuticos (National Federation of Pharmacists);</p> <p><a href="http://www.fenafar.org.br/portal/">http://www.fenafar.org.br/portal/</a></p>	 <p>Fenafar</p>
<p>(4) GAPA/SP – Grupo de Apoio à Prevenção à AIDS de São Paulo (Support Group for AIDS Prevention in São Paulo);</p> <p><a href="http://www.gapabrsp.org.br/">http://www.gapabrsp.org.br/</a></p>	 <p>GAPA GRUPO DE APOIO À PREVENÇÃO À AIDS</p>
<p>(5) GAPA/RS – Grupo de Apoio à Prevenção à AIDS do Rio Grande do Sul (Support Group for AIDS Prevention in Rio Grande do Sul)</p>	 <p>GAPA/RS</p>
<p>(6) GESTOS – Soropositividade, Comunicação e Gênero (GESTOS - HIV+, Communication and Gender);</p> <p><a href="http://www.gestospe.org.br/web/gestos/">http://www.gestospe.org.br/web/gestos/</a></p>	 <p>GESTOS Soropositividade, Comunicação &amp; Gênero</p>



<p>(7) GIV – Grupo de Incentivo à Vida (Incentive to Life Group);</p> <p><a href="http://www.giv.org.br/">http://www.giv.org.br/</a></p>	
<p>(8) Grupo Pela Vidada/RJ (Group for Life in Rio de Janeiro);</p> <p><a href="http://www.pelavidda.org.br/">http://www.pelavidda.org.br/</a></p>	
<p>(9) GRAB – Grupo de Resistência Asa Branca (Resistance Group Asa Branca);</p> <p><a href="http://www.grab.org.br/">http://www.grab.org.br/</a></p>	
<p>(10) IDEC – Instituto Brasileiro de Defesa do Consumidor (Brazilian Institute for Consumers Protection);</p> <p><a href="http://www.idec.org.br/">http://www.idec.org.br/</a></p>	
<p>(11) Projeto Esperança de São Miguel Paulista (Project of Hope São Miguel Paulista).</p> <p><a href="http://www.projesp.org.br/">http://www.projesp.org.br/</a></p>	
<p>(12) RNP+/MA - Network of People Living with HIV/AIDS Maranhão;</p> <p><a href="http://rnpvha.org.br/site/">http://rnpvha.org.br/site/</a></p>	
<p>(13) Grupo Pela Vidada/SP (Group for Life in São Paulo);</p> <p><a href="http://www.aids.org.br/">http://www.aids.org.br/</a></p>	

2. GTPI's mission is to fight to guarantee the right to health, specifically the right to pharmaceutical assistance by monitoring and struggling against the impacts of intellectual property rules on access to essential goods and knowledge. The Group conducts studies and advocacy actions to overcome the negative impact of pharmaceutical patents and other monopolistic mechanisms on the access to essential medicines and the implementation of health policies in Brazil.

3. With the intention of contributing to an effective universal periodic review process, we are hereby providing some input regarding Brazil's obligation to fulfill the human right to health, specially related to access to medicine for HIV/AIDS.

## Background information

4. In 1995 the World Trade Organization (WTO) was established with the goal of setting rules to expand the liberalization of international commerce. With the creation of WTO, several multilateral agreements were also established and incorporated by member states into their national laws. For the purpose of this submission, the most relevant of these agreements is the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement. The main change imposed by this agreement was the obligation to grant patents (a kind of intellectual property right) for all technological fields, including the pharmaceutical sector, an obligation that wasn't adopted by several countries so far, including Brazil.

5. The entrenchment of the newly established international intellectual property laws has directly impacted public health and the access to essential medicines. A major challenge for the maintenance of national policies providing for universal Access to medicines has been the increasing cost of treatment due to incorporation of new medicines protected by patents. The patents give exclusive rights to its holders and enable them to avoid third parties to produce, use, commercialize, sell or import patented inventions. The possible competitors can't enter in the market during the protection period, which is, in the case of patents for inventions, 20 years. This means that patents limit competition and create a monopoly situation, enabling patent holders to charge high prices which impacts significantly on access to medicines.

6. The TRIPS agreement is considered a "floor" in intellectual property standards. Therefore, commerce and intellectual property issues may be negotiated in other spaces. So, countries pushing for the adoption of more strict standards of protection started to seek the provisions that weren't included in TRIPS at other negotiations. These stricter measures are known as TRIPS-plus and are generally harmful to the public interest and, particularly, to the right to health. Normally these stricter provisions are adopted through free trade agreements (FTAs) negotiated with developed countries, but can be also adopted internally by the countries.

7. On the other hand, since when TRIPS was being negotiated, there was a great concern shown by developing and least developed countries regarding the potential TRIPS negative effects in guaranteeing their populations rights. Therefore, WTO member states established as a TRIPS principle that countries could adopt necessary measures to protect public health and promote public interest in key sectors to their socioeconomic and technological development (Article 8). The right to use protection measures was lately reinforced with the approval of "Doha Declaration on TRIPS and Public Health".

8. The UN Special Rapporteur on the Right to Health has addressed this subject in his report presented to the UN Human Rights Council in June 2009, in which is recommended that developing countries should include in their national legislation all of TRIPS flexibilities to promote access to medicines and also remove any TRIPS-plus measures.

9. Brazilian legislation not just foresees measures that go beyond obligations undertaken when TRIPS was signed, but also did not include some important flexibilities to protect public health. We understand that the adoption – and full utilization – of the measures of public health protection (flexibilities) stipulated as well as the exclusion of TRIPS-plus provisions could mitigate the negative impacts of

pharmaceutical patents on access to medicines, such as high pricing practices in monopolistic situations.

### **The HIV/AIDS epidemic in Brazil**

10. The policy of universal access to antiretroviral (ARV) treatment in Brazil has produced some important results. From 1997 to 2004, the country saw a 40% reduction in mortality and a 70% reduction in morbidity as a direct consequence of HAART. 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, generating a savings of US\$2.3 billion. These figures demonstrate that access to proper ARV treatment over the past years has substantially transformed the lives of patients and the methods of controlling HIV infection, improving quality of life for people living with 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 assuring universal access to treatment for all who need it<sup>1</sup>.

11. Brazil is one of the few countries in the world that provides universal free access to AIDS treatment. The National Department of STD/AIDS/VH estimates that some 630,000 people are infected with the HIV virus in Brazil. Of these, 190,000 undergo ARV treatment. Data from the Ministry of Health indicates that around 33% of the budget for the procurement of antiretroviral drugs in Brazil is spent on nationally produced medications in contrast with 67% spent on imported patented drugs. The fact that such an immense portion of the budget is being spent on patented medicines has placed the sustainability and universality of this healthcare policy in jeopardy, as recognized by the Ministry of Health in 2005<sup>2</sup>.

12. To live more dignified lives, access to proper treatment is crucial for thousands of people living with HIV/AIDS in Brazil. The Brazilian government has a legal obligation to provide full treatment to all who need it. The initial success of the national STD/AIDS Program has largely been attributed to the local manufacture of drugs that did not enjoy patent protection in Brazil. Nevertheless, the growing portion of ARV drugs – patented or with patent pending—could make the national policy of universal free access to AIDS treatment unsustainable<sup>3</sup>.

### **The Brazilian IP legislation**

13. Until 1996, intellectual property legislation in Brazil did not grant patents for pharmaceutical products. Even though the TRIPS Agreement granted a delayed period until 2005 to developing countries to incorporate its standards, in 1996 Brazil approved its new intellectual property law. This change had a great impact in the Brazilian public health system, overhauling the existing legal regime that permitted medicines to be produced locally at affordable prices. Especially regarding the AIDS treatment, until 1997 Brazil based its answer to the epidemic in the policy of universal free access to antiretroviral drugs, made possible especially through the national production of generic drugs.

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<sup>1</sup> REIS, Renata; VIEIRA, Marcela Fogaça; CHAVES, Gabriela. Access to medicines and intellectual property in Brazil: a civil society experience. *In* Intellectual property rights and access to ARV medicines: civil society resistance in the global South. Organized by: Renata Reis, Veriano Terto Jr. e Maria Cristina Pimenta. Rio de Janeiro: ABIA, 2009. p. 15.

<sup>2</sup> Idem. p. 16.

<sup>3</sup> Idem. pp. 16-17.

14. Since then, many challenges have emerged that threaten the country's policy of universal access to AIDS medicines. The greatest such challenge has been the increase in the cost of treatment with new patented drugs that are not manufactured domestically. Medical guidelines increasingly require these drugs to substitute or complement previous treatments. In addition to this, there has also been an increase in the number of patients receiving treatment, both because there is an increasing number of diagnosed people and new WHO recommendations to start the treatment earlier. This constant increase in the cost of antiretroviral treatment has jeopardized the sustainability and universality of this healthcare policy.

15. Brazil did not take advantage of the 10-year transition period granted by the WTO to recognize patents in the field of medicines. This period, offered to developing countries that did not previously recognize pharmaceutical patents, could have allowed domestic pharmaceutical companies to strengthen their capacity to compete with transnational drug companies specializing in research and development (R&D). Brazil used less than two years of the transition period, altering its law in 1996, which came into operation in May 1997.

16. Furthermore, Brazilian legislation failed to adopt some of the flexibilities permitted by TRIPS and, in some respects, went much further than what was required by the Agreement, including some TRIPS-plus measures. This was the result of a research recently conducted by Conectas Direitos Humanos<sup>4</sup>, member of GTPI/Rebrip.

17. A number of law bills are currently under analyses by Brazilian Legislative branch. Some of them aim to include or improve the provisions related to public health flexibilities and other aim to adopt some new TRIPS-plus measures. Below, we bring some of these bills as examples of how Brazil could improve its legislation to better protect the right to access to essential medicines.

18. Bill of Law 139/1999. Parallel imports, an important public health flexibility, has been incorporated into Brazilian law, albeit only in a limited way, since its use is restricted to situations in which a compulsory license has been issued in virtue of abuse of economic power or in cases of national emergency and public interest. There is currently a law bill (PL 139/99) working its way through the National Congress to incorporate this flexibility in full. This is an extremely crucial mechanism for policies on drug access, since multinational pharmaceutical companies usually set different prices for the same drug in different countries. If domestic legislation permitted parallel imports, Brazil would be able to import medicines from wherever they were sold at the lowest price<sup>5</sup>. This bill has been under analyses for almost 12 years in the House of Representatives, but parliamentarians still haven't decided for its approval or rejection. This delay has imposed great financial loss for the public health system, since the government, under current legislation, is not able to import medicines from other countries where they are sold at a lower price.

19. Compulsory licensing has been incorporated into Brazilian legislation and can be utilized for a number of reasons, including in cases of national emergency or public interest declared by the Federal

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<sup>4</sup> CONECTAS Direitos Humanos. "Propriedade intelectual para produtos farmacêuticos: um estudo sobre a adequação legislativa sob a ótica de saúde pública e do direito humano à saúde", supported by Brazilian Ministry of Health and by UNESCO. 2011. Preliminary results available at (in Portuguese only): <http://www.deolhonaspateentes.org.br/media/file/seminario%20abril%202011/Marcela%20Vieira%20-%20legislacao.pdf>.

<sup>5</sup> REIS, Renata et. all. op. cit. p. 24.

Executive Authorities. However, there is still plenty of room to improve the use of this flexibility in Brazil. Bill of Law 139/1999 and its appendices also aims to expand the use of compulsory license in case of no local manufacture of the patented product by the patentee and also seek to expand the non-commercial public use of patents, which is also a form of use of the patented product that does not depend on the authorization of the owner<sup>6</sup>. We believe that the approval of this bill could improve access to medicines in Brazil, by enhancing already available mechanisms.

20. Bill of Law 22/2003. This Bill of Law plans 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<sup>7</sup>. The analysis of the bill by the parliamentarians was favorable to the approval of the bill, however it still awaits final approval in the House of Representatives. We believe the approval of this bill could enhance access to AIDS medicines in Brazil

21. Bill of Law 230/2003. This bill aims to include all the substances needed to manufacture drugs by public laboratories, which will be distributed free of charge in the public health system, among the cases that do not apply to the patentee the right to prevent others from making, using, offering for sale or importing the product or process under patent protection. The approval of this Bill would allow the production of patent-protected medicines by national public laboratories regardless of authorization of the patentee, provided that the allocation of the drug was for free distribution by public health system. The production cost of these drugs by public laboratories would be lower than the price charged by the patentee, allowing savings of public resources and increasing people's access to medicines<sup>8</sup>.

22. Bill of Law 2511/07 and Bill of Law 3995/08. Bill of Law 2511/07 aims to prohibit patent protection for new uses for known products. Bill of Law 3995/08 aims to prohibit patent protection for polymorphs. Both are making their way through the Brazilian Congress. Although these types of patent protections are extremely harmful to public health, they are being granted by the Brazilian patent office (INPI). Patent protection for use claims allows the grant of protection that does not represent real pharmaceutical innovations, since what is being protected is a new use of a product that is already known. Polymorphism is an intrinsic property of matter in its solid state, that is to say, they may exist in different physical forms, which may have different properties more or less pharmaceutically significant. Since polymorphism is a natural property, polymorphs cannot be considered a human invention; they are discovered normally as part of routine experimentation. Therefore, they are not patentable. The decision of granting patent protection for both use claims and polymorphs is related to the definition of the patentability standards, which each country has the possibility to interpret in its own way. The definition of such criteria constitutes a key aspect of patent policy, with implications in other areas, such as industrial and public health policies. The patentability standards – novelty, inventive step and industrial application – may be interpreted in different ways, and countries and specialists do not

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<sup>6</sup> CONECTAS Direitos Humanos. op. cit. slide 21.

<sup>7</sup> REIS, Renata et all. op. cit. p. 38.

<sup>8</sup> CONECTAS Direitos Humanos. op. cit. slide 25.

necessarily adopt the same interpretation. The interpretation of the patentability standards is not a technical issue, but a political decision, especially in the pharmaceutical field<sup>9</sup>. We believe there is no need to amend Brazilian legislation in order to deny patent applications for new uses of known products or for polymorphs. However, since the Brazilian patent office (INPI) considers that there is a need to amend the law for that purpose, the approval of this bill of law could help enhance access to medicine in Brazil.

23. Bill of Law 6654/2009. This Bill of Law intends to condition the registration of a drug to the expiry of its patent. This practice is known as linkage, a TRIPS-plus measure that establishes a relation between drug registration and patent protection. In practice, linkage between patents and drug registration raises an additional barrier to the entrance of generic drug on the market, since it links the start of the registration process for generic versions of a drug to the expiry of the patent. In other words, it delays the onset of competition and amounts to a de facto extension of patent terms, which is completely at odds with public health interests. If this bill is approved, it will effectively remove the Bolar Exception, an important TRIPS-flexibility, which is already being used by Brazilian producers, from Brazilian law and would include an additional obstacle to access to essential medicines in Brazil<sup>10</sup>. Therefore, this bill should be reject by the Legislative.

24. Besides the bills of law current in analyses by the Legislative branch, we believe the adoption of other legislative measures could also help to enhance access to medicine in Brazil. Below, we bring some of these measures.

25. Brazilian law provides the possibility to extend beyond 20 years the term of a patent due to delay in its concession. As seem above, the granting of a patent causes negative impact on access to the patented product by limiting the option to purchase a single vendor, which markets the product in a monopoly situation. Thus, the term of the patent should be limited to that has been agreed on international level and any kind of extension should not be allowed<sup>11</sup>. Therefore, we urge Brazil to remove any possibility of extension of patent protection beyond 20 years from its IP legislation.

26. Brazilian law currently provides the possibility of third parties to challenge a patent after it has been granted, in the judicial or administrative level. However, with regard to third party participation prior to grant of the patent, the law provides only the mechanism of presentation of "inputs for the examination", which is very fragile in the face of other mechanisms such as the pre-grant opposition. We believe that a change in legislation to strengthen the participation of interested parties in the process of patent applications analyzes before it is granted would bring benefits to public health<sup>12</sup>.

### **Health sector participation in analyzing pharmaceutical patent applications: ANVISA's prior consent**

27. Health sector participation in analyzing pharmaceutical patent applications was incorporated into the Brazilian IP law in 1999. This mechanism determines that pharmaceutical patents may only be

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<sup>9</sup> REIS, Renata et all. op. cit. pp. 40-42.

<sup>10</sup> REIS, Renata et all. op. cit. pp. 38-39. An identical Bill of Law was initially proposed at the Senate (PLS 29/2006). The proposal was reject at the Senate and then presented at the House of Representatives, where it is still under analyses (PL 654/2009)

<sup>11</sup> CONECTAS Direitos Humanos. op. cit. slide 41.

<sup>12</sup> Idem. slide 42.

awarded with the prior consent of the Brazilian National Sanitary Supervision Agency (ANVISA), the government agency responsible for the safety and quality of medicines in Brazil. Given the importance of this topic and the essential nature of pharmaceutical products, Brazilian lawmakers considered patent-granting important enough for each case to warrant the most rigorous and technical examination possible by the State. Prior consent by ANVISA is not, therefore, simple interference in the patent-granting procedure. It is a measure to protect patients because it prevents drug patents to be awarded when they are undeserved<sup>13</sup>.

28. Bill of Law 3709/2008. According to Brazilian legislation on intellectual property, applications for pharmaceutical patents must obtain the prior consent of ANVISA. Prior approval is required in virtue of the importance of public health. However, the pharmaceutical industry and the Brazilian patent office (INPI) are against ANVISA's prior consent. In several occasions, ANVISA's prior consent was questioned in the Executive, the Legislative and the Judiciary. In the Legislative, there is a bill of law (3709/2008 and appendix 7965/2010) that aims to establish that ANVISA's prior consent is only necessary in case of patent claims made by the pipeline mechanism and not all patent applications in the pharmaceutical sector<sup>14</sup>. We believe that the approval of this bill and its appendix will be very prejudicial to public health, since it will remove ANVISA from the analyses of almost all patent applications.

29. In the Executive branch, a legal opinion adopted by Advocacia-Geral da União - AGU (Advocacy-General of the Union) severely weakened ANVISA's participation in the analyses of patent application in the pharmaceutical sector. According to that legal opinion, ANVISA's analysis should stick to investigate potential harmful effects to human health of the product and services and ANVISA could not analyze the fulfillment of the patentability criteria. AGU's official interpretation of the law is a serious setback on the defense of high standards of patentability for pharmaceutical patents and the use of protective measures for health in relation to intellectual property rights. GTPI, in January 2011, sent an urgent appeal to the United Nations Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health regarding this legal opinion adopted by AGU.

### ***Pipeline patents***

30. In 2008, during Brazil's first Universal Periodic Review, GTPI submitted information regarding the revalidation patents know as *pipeline* patents and its harm to public health. Unfortunately, few have changed since then.

31. The pipeline mechanism is a provision that validates patents from fields of technology that Brazil had not traditionally recognize as patentable, such as food and pharmaceutical products. Pipeline patents were granted during the vacation legis period of Brazil's current intellectual property law, which was altered in 1996. Pipeline patents have granted protection to inventions that were already in public domain and no longer qualified for patent protection. In fact, the products protected by the pipeline mechanism were already known in the state of art, since they had already been published abroad. The concession of the pipeline patents is, therefore, a frontal violation of the principle of non-withdrawal from the public domain, whereby knowledge, once in the public domain, can never again be removed.

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<sup>13</sup> REIS, Renata et all. op. cit. p. 42.

<sup>14</sup> Idem. p. 42.



32. Pipeline patents have had a significant impact on sensitive areas of social interest and also on the country's technological and economic development. According to data released by the INPI, within the legal timeframe of one year from the publication of Law 9.270/96, 1,182 pipeline requests were filed, of which more than half have already been granted and the rest is under review. A report commissioned by GTPI estimates that these pipeline patents have cost Brazil in the billions of dollars.

33. At the end of 2007, GTPI presented the Brazilian Prosecutor General with a petition that demonstrated the unconstitutionality of the two articles of Brazil's industrial property legislation that created the pipeline mechanism. The petition called on the Prosecutor General to bring a Direct Action of Unconstitutionality (ADI) against the pipeline mechanism before the Supreme Court, since civil society organizations do not have the standing to file this kind of legal case. Through ADI it is possible to question whether the determined legislation is consistent with the Federal Constitution. The Supreme Court – the highest court of law in Brazil – judges directly the ADI, and a declaration of unconstitutionality results in the law in question being removed from the legal system to prevent it from having any legal effect.

34. In May of 2009, the Brazilian Prosecutor General filed an ADI before the Brazilian Supreme Court (STF) questioning the constitutionality of the pipeline mechanism. In January 2011, GTPI conducted a study that shows that between May 2009 and December 2010 Brazilian government spent R\$ 123 million more to buy the patented version of four drugs protect by patents granted under the pipeline mechanism than it would have spent if it had bought the generic version of those medicines available in the international market<sup>15</sup>. This study shows the great loss of public resources that is still caused by pipeline patents and highlights the importance of STF making a swift decision of the case.

### Public Private Partnerships

35. In the year of 2011, the Brazilian government came to public to announce public private partnerships with antiretroviral patent owners to transfer the technology and produce medicines locally. This was a Brazilian government political choice in a new scenario, in which the generic competition tends to diminishes for several reasons worldwide, specially due to fact that all developing countries had to become TRIPS-compliant in 2005. However, it is important to highlight the process surrounding this choice. Historically, the Brazilian response to the HIV/Aids epidemic – and the Brazilian Aids program formulation and execution itself - was marked by a crucial civil society participation. Nonetheless, in these contracts made between the Brazilian government and the pharmaceutical companies there is a move in the opposite direction, because civil society groups are facing lack of information and transparency, since the agreements are being firmed and announced without previous debates and remaining in secret, despite claims for discussion on the terms agreed<sup>16</sup>.

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<sup>15</sup> GTPI. Cálculo estimado do prejuízo monetário causado pela compra de quatro medicamentos selecionados protegidos por patentes *pipeline*. 2011. Available at (in Portuguese only): <http://www.deolhonaspateentes.org.br/media/file/Notas%20GTPI%20-%202011/GTPI%20-%20calculo%20pipeline%20%28final%29.pdf>.

<sup>16</sup> GTPI. Carta de Preocupações do GTPI a respeito das Parcerias Público-Privadas anunciadas pelo governo. 2011. Available at (in Portuguese only): [http://www.deolhonaspateentes.org.br/media/file/Notas%20GTPI%20-%202011/Carta%20GTPI\\_Preocupa%C3%A7%C3%B5es\\_Final\\_Site.pdf](http://www.deolhonaspateentes.org.br/media/file/Notas%20GTPI%20-%202011/Carta%20GTPI_Preocupa%C3%A7%C3%B5es_Final_Site.pdf).

36. Without having access to the terms of those contracts, which are involving public laboratories, the civil society has not been able to have an opinion regarding the PPPs neither to exercise its right to social control of public policies. Some of the medicines that are object of these partnerships have patent applications still pending in Brazil, some of which might not fulfill the patentability criteria. However, in the negotiations it seems that the Brazilian government is considering the patents already granted, which could lead to a higher price to be paid for a technology that should be in public domain in Brazil<sup>17</sup>. This lack of transparency must be addressed also because the terms of the contracts can have a broader effect in the future of the response to the HIV/Aids epidemic both in Brazil and beyond, especially the pricing conditions.

### Shortages

37. The monopoly provided by patent protection has a negative impact on access to medicines not only because it enables patent owners to charge high prices but also because relying on a single provider can lead to supply problems such as shortages. In February 2007, for example, the Brazilian National Program of DST, AIDS and Viral Hepatitis released a technical note stating the interruption of prescription and substitution of the drug abacavir due to problems in the contract with the producer that lead to delivering delays. In the same year, the government suspended the distribution of nelfinavir and recommended its substitution after the company Roche announced the retrieval of the drug. In both cases, the drugs were available in the international market, including with more than one option of generic versions. However, Brazil couldn't access these versions because of the monopoly situation. Shortages have occurred very often in Brazil in the last years and due to lack of transparency by authorities it isn't possible to assess in which cases they happened because of problems with providers enjoying a monopoly situation. According to patents law, in these cases a compulsory license could be justified on the grounds that the provider isn't addressing properly the demand. It's worth saying that substitution and shortages have a very negative impact on patient's adherence to treatment<sup>18</sup>.

### Final remarks

38. Brazil has taken the lead in recent years to ensure that intellectual property protection rules adopted on an international level do not pose a threat to the public health systems of developing nations. However, on a domestic level, the country has adopted an approach that consistently gives preference to intellectual property rights before public health, in stark contrast to the attitude it displays in international forums.

### Recommendations

39. We believe that the implementation of the following recommendations could help Brazil to fulfill its obligation to provide access to essential medicines for all in need:

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<sup>17</sup> Idem.

<sup>18</sup> GTPI. Carta sobre o desabastecimento do atazanavir. 2011. Available at (in Portuguese only): <http://www.deolhonaspateentes.org.br/media/file/Notas%20GTPI%20-%202011/Carta%20sobre%20desabastecimento%20do%20Atazanavir.pdf>.



- a. Amend its national legislation in order to include – in full – all the intellectual property related measures that could protect the public health and to remove all and not include any new measure that go beyond what was already agreed in international fora, such as TRIPS-plus measures. That includes, among other measures, the approval of the following Bills of Laws: 139/99, 22/03, 230/03, 2511/07 (and its appendix 3995/08). And also the rejection of the following Bills of Laws: 6654/2009, 3709/2008 (and its appendix 7965/2010). It also includes the removal of any provision in the law that extends the term of patent protection beyond 20 years and the approval of measures that strengthen third parties participation on the analysis of patent application, such as pre-grant oppositions.
- b. Not include any new TRIPS-plus measure in its legislation through the negotiation of Free Trade Agreements.
- c. Maintain ANVISA's prior consent for all patent applications in the pharmaceutical sector, including the analysis of the fulfillment of the patentability criteria established by Brazilian law.
- d. Annul all the patents granted by the pipeline mechanism, which could be done by judging pipeline patents unconstitutional as requested in ADI 4234 currently submitted to the Brazilian Supreme Court.
- e. Set up a transparent mechanism through which civil society can follow-up production, buying and distribution procedures of ARVs, making available detailed and updated information about fulfillment of deliveries.
- f. Observe principles of transparency and social control in the implementation of policies such as the Public-Private Partnerships for the production of ARVs, and establish a concrete and wide debate with society about the current policy options available for supplying ARVs, such as the use of TRIPS flexibilities.