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CONSEIL DES DROITS DE L'HOMME**

**UNITED NATIONS
OFFICE OF THE UNITED NATIONS
HIGH COMMISSIONER FOR HUMAN RIGHTS**

**SPECIAL PROCEDURES OF THE
HUMAN RIGHTS COUNCIL**

**Mandate of the Special Rapporteur on the right of everyone to the enjoyment of the highest
attainable standard of physical and mental health.**

REFERENCE: AL Health (2002-7)
BRA 5/2011

9 September 2011

Excellency,

I have the honour to address you in my capacity as Special Rapporteur on the right of everyone to the highest attainable standard of physical and mental health pursuant to the General Assembly Resolution 60/251 and to Human Rights Council Resolution 15/22.

In this connection, I would like to draw the attention of your Excellency's Government to information I have received concerning the decisions of the Advocate-General of the Union on the prior consent of the National Health Surveillance Agency (ANVISA) to patents in the pharmaceutical area and their impact on access to medicines in Brazil.

According to the information received:

It is alleged that the dispute between the National Institute of Industrial Property (INPI), Brazil's patent authority, and ANVISA, which gives prior consent to patents granted by INPI, prompted the Advocate-General of the Union to intervene and review the duties of INPI and ANVISA with regard to patent applications in the pharmaceutical area.

In January 2011, the Advocate-General of the Union reportedly issued a final legal opinion, an official interpretation of the law to be observed by INPI and ANVISA, according to which ANVISA would henceforth review only possible adverse health effects of patent applications. The final opinion was allegedly similar to a preliminary decision of the Advocate-General of the Union, which the Ministry of Health, Ministry of Science and Technology and ANVISA had requested to review on the grounds of possible implications for the public health in Brazil and technical difficulties of analyzing adverse health effects of a product through a patent application.

In May 2011, the Chamber of Deputies of Brazil reportedly addressed the legal opinion of the Advocate-General of the Union and discussed its ramifications on ANVISA's role. A possible creation of a working group of experts from ANVISA and INPI was reportedly discussed, among other things. During the debate, the Advocate-General of the Union allegedly defended the prior consent of ANVISA for pharmaceutical patents while reiterating the importance of INPI's final decision on patent approvals.

It is alleged that the Advocate-General of the Union's final legal opinion transformed ANVISA's prior consent into a pre-grant opposition submitted for INPI's discretion and appeared to undermine the spirit of the Brazilian Industrial Property Law.

While I do not wish to prejudge the accuracy of these allegations, I would appreciate information from your Excellency's Government on the steps taken with a view to ensuring the right to the highest attainable standard of health in the context mentioned above. This right is reflected, *inter alia*, in article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) (acceded on 24 January 1992), which provides for the right of everyone to the enjoyment of the highest attainable standard of mental and physical health. This includes an obligation on part of all States parties to ensure that health facilities, goods, and services are accessible, acceptable, of good quality and available to everyone, especially the most vulnerable or marginalized sections of the population, without discrimination.

General Comment No. 14 of the Committee on Economic, Social and Cultural Rights holds that access to essential medicines is a core obligation of the right to health and States must comply immediately with this non-derogable obligation regardless of resource constraints. The Committee stated that State parties should ensure that the right to health is given due attention in international agreements and, in relation to the conclusion of other international agreements, State parties should take steps to ensure that these instruments do not adversely impact upon the enjoyment of the right to health. General Comment No. 14 also states that there is a strong presumption that retrogressive measures taken in relation to the right to health are not permissible. If any deliberately retrogressive measures are taken, the State party has the burden of proving that they have been introduced after the most careful consideration of all alternatives and that they are duly justified by reference to the totality of the rights provided for in the Covenant in the context of the full use of the State party's maximum available resources.

The Committee on Economic, Social and Cultural Rights also stipulates that community participation and consultation in policymaking is central to the right to health. In order to develop sound policies, the relevant and affected communities and groups must have input into the policymaking process and be allowed access to negotiations and meetings related to these policies. Moreover, the rights to information and to participation

in the conduct of public affairs are essential dimensions of the right to health, as well as self-standing rights. The formulation of policies that affect the enjoyment of the right to health should be transparent in order to allow individuals to determine what, if any, impact such policies will have on their right to health.

Furthermore, I would also like to draw the attention of your Excellency's Government to General Comment No. 17 of the Committee on Economic, Social and Cultural Rights, which holds, in paragraph 35, that: "States parties [to ICESCR] thus have a duty to prevent unreasonably high costs for access to essential medicines, (...) from undermining the rights of large segments of the population to health (...)."

Finally, the Trade-Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organization (WTO) created specific permissible flexibilities on the implementation of international patent rights in recognition of the developmental concerns of developing countries, particularly with respect to health. The 2001 Doha Declaration on TRIPS and Public Health by WTO reaffirms these flexibilities, by stating that "the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility [to promote access to medicines for all]." As a signatory to the Doha Declaration and Member of the WTO, your Excellency's Government should be guided by the Declaration's affirmation that "the [TRIPS] agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all."

In view of the urgency of the matter, I would appreciate a response on the initial steps taken by your Excellency's Government to safeguard the right to health in compliance with the above international instruments.

It is my responsibility under the mandate provided by the Human Rights Council to seek to clarify all cases brought to my attention. Since I am expected to report on these cases to the Council, I would be grateful for your cooperation and your observations on the following matters:

1. Are the facts alleged in the above summary accurate?
2. Please provide details of any actions taken to ensure consultations with civil society and other relevant stakeholders with regard to the proposed changes to ANVISA's prior consent on pharmaceutical patents.
3. Please provide details of any actions taken by your Excellency's Government to ensure that the decisions of the Advocate-General of the Union would not have negative impact on the public health and access to medicines in Brazil.

I undertake to ensure that the response of your Excellency's Government to each of these questions is accurately reflected in the reports that will be submitted to the Human Rights Council for its consideration.

Please accept, Excellency, the assurance of my highest consideration.

Anand Grover
Special Rapporteur on the right of everyone to the enjoyment of the
highest attainable standard of physical and mental health