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**Promotion and protection of all human rights, civil,
political, economic, social and cultural rights,
including the right to development**

Written statement* submitted by the American Association of Jurists, a non-governmental organization in special consultative status

The Secretary-General has received the following written statement which is circulated in accordance with Economic and Social Council resolution 1996/31.

[14 February 2017]

* This written statement is issued, unedited, in the language(s) received from the submitting non-governmental organization(s).

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Panel discussion on access to medicines: a new approach is needed

The right to health and access to medicines

The human right to health is legally recognized in many international human rights treaties, regional human rights instruments and most of national legislations. It is comprehensively enshrined in the International Covenant on Economic, Social and Cultural Rights (ICESCR) at its Article 12.1 and it is also interpreted in General comment n°14 by the Committee on Economic Social and Cultural Rights (CESCR).

As interpreted by the CESCR, the right to health is “*an inclusive right extending not only to timely and appropriate health care but also to the underlying determinants of health, such as access to safe and potable water and adequate sanitation, an adequate supply of safe food, nutrition and housing, healthy occupational and environmental conditions, and access to health-related education and information, including on sexual and reproductive health*”.

Furthermore, as stated by Mr. Anand Gover, former Special Rapporteur on the right to health, “*Access to medicines is an integral component of the right to health* ». More recently the HRC recognized in resolution A/HRC/32/15 that access to medicines constitutes one of the fundamental elements of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

Years of discussions must lead to actions

More than ten years of discussions have not led to major changes towards a full access to safe, effective and affordable medicines. As discussions continue, millions of peoples still do not have access to essential medicines and keep dying of diseases that can be treated. In spite of many recommendations put forth by a range of working groups and included in other initiatives, such as the Commission on Intellectual Property, Innovation and Public Health (CIPIH, 2006), the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA, 2009) and the Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG, 2012), nothing significant has been put in place to meaningfully address the current barriers to access to medicines. The current WHO strategic Work Plan put in place by resolution WHA 69.23 is in our view, a way to pretend that actions are taken, while actually perpetuating the unsustainable status quo.

Policy incoherence

In November 2015, after the adoption of the Sustainable Development Goals (SDGs), the United Nations Secretary General decided to convene a High Level Panel on Access to Medicines (UNHLP) with the mandate to “*review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies*”. The panel drew upon existing mandates at the WHO and WHO discussions that have been ongoing for over 15 years and are not yet concluded. The report released by the UNHLP in September 2016 contains a range of meaningful recommendations.

Intellectual Property (IP) rules, trade rules and Human Rights (HR) were developed in different contexts, for different reasons and were pursuing different objectives. Indeed, historically, these different rules used to coexist in separate legal regimes, thus leading to a policy incoherence for the mere reason that those rules were, to some extent, created in

isolation from each other. Policy incoherence appears when the interests arising from trade rules and IP are in conflict with public health and the right to health, as enshrined in International Human Rights Law (IHRL).

The adoption of the Agreement on Trade-Related aspects of Intellectual Property rights (TRIPs) in 1995 has led to the globalization of patent rules, especially on pharmaceutical products. Patenting drugs has raised many ethical issues, especially when those patents resulted in high prices and were therefore an obstacle to the full access to life-saving medicines for patients. That situation has created incoherence with the obligations of States relating to access to medicines. While States, under IHRL, have to take proactive measures to protect, promote and fulfil the right to health, the global profit-driven monopoly-based R&D system does not aim at responding to the effective health needs of the patients, and therefore leads to policy incoherence. For example, the current predominant R&D model doesn't create enough incentives to invest in research on innovation for diseases that affect the poorest. And when new medicines that have the potential to save lives are created, they are often too expensive, resulting in a very high economic burden on patients and/or on institutions of reimbursement in both developing and developed countries, when that money could have been allocated to other projects of development. In the context of the global financial crisis, States, especially developed ones, are adopting austerity measures to reduce the State debt. These policies have led to a reduction of the resources generally allocated to progressively realize the right to health and other HR, resulting again in policy incoherence.

Probably aware of the potential conflicts between the TRIPs and the obligations arising from the right to health, WTO Member States decided to incorporate flexibilities that would allow them to adapt and design their national legislation, in order to fulfil their human rights obligations, especially the right to health. However, the pressure from developed countries and pharmaceutical companies has led to the underutilization of these flexibilities, especially compulsory licenses.

To correct the potential misalignment between trade rules, IP rules and HR, WTO Member States adopted the Doha Declaration on the TRIPs Agreement and Public Health in 2001, which had the objective to interpret the Agreement in accordance with public health obligations and reaffirm the importance of the TRIPs flexibilities, as a core element of the TRIPs. In this regard, the adoption of the recent amendment (new Article 31bis) of the TRIPs Agreement, which allows countries producing generic medicines under compulsory licence to export all of the medicines to least-developed countries that lack manufacturing capacity themselves, has to be welcomed. However, despite these evolutions, some recent events, for example in Colombia, have shown that this issue is still a very critical one. Undue pressure from developed countries and pharmaceutical companies unfortunately remains a widespread practice and must be strongly condemned and fought.

Furthermore, we witnessed a troubling trend these recent years in connection with the adoption of Free Trade Agreements (FTAs) that include TRIPs-plus provisions. Those provisions go beyond the provisions of the TRIPs Agreement and have therefore the potential to pave the way to several human rights violations and to impede the use of TRIPs flexibilities, therefore aggravating policy incoherence.

Finally, many States have shown strong commitments to implement IP and trade rules at the national level, putting aside their obligations under IHRL, leading to incoherence within States.

Actions to be taken and recommendations

The American Association of Jurists recommends that States:

- in conformity with the UN Charter, recognize the superiority of Human Rights over trade rules and IP rules;
- explore new R&D models that are public-health sensitive, such as delinkage¹;
- consider the negotiation of an R&D Convention that would ensure coordination and sustainable financing, by delinking the cost of R&D with the final prices of drugs, as recommended by the CIPIH (2006), the GSPOA (2008), the CEWG (2012) and now by the UNHLP (2016);
- demand transparency and accountability to pharmaceutical companies regarding their skyrocketing profit margins and the cost of R&D;
- raise their investments in public health research and development and ensure that the outcomes are made available at affordable prices.
- make full use of the TRIPs flexibilities provided in the TRIPs Agreement and refrain from adopting FTAs that include provisions that hinder the realization of Human Rights, especially the right to health and access to medicines;
- register complaints against undue political and economic pressure, which includes taking punitive measures against offending WTO Members.

Furthermore, the American Association of Jurists recommends that the Human Rights Council asks the HRC Advisory Committee to undertake a study that assesses the effects of FTAs containing TRIPs-Plus provisions on Access to Medicines and public health.

Finally, the American Association of Jurists recommends to the Special Rapporteur to uphold the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, to pay immediate attention to the UNHLP report and provide guidance to implement its recommendations.

¹ Delinkage describes the idea that temporary monopolies and the associated high drug prices should not be used to fund pharmaceutical research and development, as well as a set of policy proposals that would replace monopolies and high prices with alternative incentives. Collectively, delinkage would transform the business model of the pharmaceutical industry in order to expand access, improve outcomes and reduce costs.