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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)
OTH 9/2012

21 August 2012

Dear Mr. Fule,

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

I would like to draw the attention of your EU institution information I have received concerning **the impact of article 9 of the draft Deep and Comprehensive Free Trade Agreement, currently being negotiated between the European Union and the Republic of Moldova, on access to medicines in the Republic of Moldova.**

According to the information received:

The European Union (hereafter "EU") and the Republic of Moldova (hereafter "Moldova") have reportedly been negotiating a Deep and Comprehensive Free Trade Agreement (DCFTA). It is alleged that article 9 of the draft DCFTA contains a "TRIPS-plus" provision on data exclusivity. It is further alleged that if this data exclusivity provision is adopted, manufacturers of generic medicines would not be able to refer to clinical test results of originator drugs for a maximum period of eleven years. It is also alleged that this will ensure a monopoly by manufacturers of originator drugs and that manufacturers of generic drugs will be unable to enter the market and provide cheaper alternatives to originator drugs for a maximum period of eleven years.

It is further alleged that were article 9 to be adopted, it would potentially have a significant, negative impact on the ability of major segments of the population in Moldova to afford a range of medications, including antibiotics, antiretrovirals and medicines for the treatment of tuberculosis and cancer. Furthermore, the data exclusivity regime could allegedly lead to legal claims related to intellectual property, which would create an uncertain procurement and supply environment, driving prices for medicines up.

While I do not wish to prejudge the accuracy of these allegations, I would highly appreciate information from your institution on the steps taken with a view to ensuring the right to the highest attainable standard of health in the situation mentioned above. This right is reflected, *inter alia*, in article 12 of the International Covenant on Economic, Social and Cultural Rights, of which every EU Member State is a party and which provides for the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. This includes an obligation on part of all States 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.

I also call your attention to General Comment No. 14 of the Committee on Economic, Social and Cultural Rights, which holds that the right to health imposes three types of obligations on States (para.33): the obligations to respect (refrain from interfering directly or indirectly with the enjoyment of the right), protect (prevent third parties from interfering with them) and fulfil (facilitate, provide and promote those rights). The General Comment also elaborates that access to essential medicines is a minimum core obligation of the right to health and States must comply immediately with this non-derogable obligation regardless of resource constraints (para.43).

The right to health also requires States to recognize the essential role of international cooperation and comply with their commitment to take joint and separate action to achieve the full realization of the right to health (para.38). In order to comply with their international obligations in relation to the right to health, States have to respect the enjoyment of the right to health in other States; should ensure that the right to health is given due attention in international agreements; and, in relation to the conclusion of other international agreements, should take steps to ensure that these instruments do not adversely impact upon the right to health (para.39). States also have an obligation to ensure that their actions as members of international organizations take due account of the right to health (ibid.). Moreover, the General Comment notes that all members of society, including intergovernmental and non-governmental organizations have a responsibility towards the realization of the right to health (para.42). Accordingly, both the EU and its Member States are obligated to respect, protect and fulfil the right to health.

I would also like to draw your attention to Article 168 of the Treaty on the Functioning of the European Union, which states that a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities. The EU Strategic Framework and Action Plan on Human Rights and Democracy, adopted by the Council of the European Union on 25 June 2012, include the commitment that "The EU will promote human rights in all areas of its external action without exception. In particular, it will integrate the promotion of human rights into trade, investment..."

Furthermore, the need for public health to be taken into consideration in negotiating such agreements was highlighted in resolution of 12 July 2007 (P6_TA

(2007)0353) of the European Parliament, which called upon the European Council to take into consideration the need to protect public health in support of the Doha Declaration and refrain from negotiating "TRIPS-plus" provisions. It specifically called on the European Council "to meet its commitments to the Doha Declaration [on TRIPS and Public Health] and to restrict the Commission's mandate so as to prevent it from negotiating pharmaceutical-related "TRIPS-plus" provisions affecting public health and access to medicines, such as data exclusivity…" The Resolution also "encourages the developing countries to use all means available to them under the TRIPS Agreement, such as compulsory licences and the mechanism provided by Article 30". TRIPS and the Doha Declaration specifically allow for countries to protect the right to health by making use of flexibility mechanisms provided for by TRIPS. Article 9 of the draft DCFTA would be deemed contrary to the spirit of the Resolution as due to the introduction of the "TRIPS-plus" provision on data exclusivity it could hinder access to medicines in the Republic of Moldova.

I also wish to call your attention to the conclusions adopted by the Council of the European Union on the EU role in Global Health (3011th Foreign Affairs Council meeting in Brussels, 10 May 2010), in which it "calls on the EU and its Member States to act together in all relevant internal and external policies and actions by prioritizing their support on strengthening comprehensive health systems in partner countries, which are central to all global health challenges" (point 5), and adds that "This support shall ensure that the main components of health systems- health workforce, access to medicines, infrastructure and logistics, financing and management- are effective enough to deliver universal coverage of basic health care, through a holistic and rights bases approach" (point 6). In addition, the Council concludes that "the EU should support third countries, in particular LDCs, in the effective implementation of flexibilities for the protection of public health provided for in TRIPs agreements, in order to promote access to medicines for all, and ensure that EU bilateral trade agreement are fully supportive of this objective" (point 16 (a)).

Finally, I would like to recall the work of the EU's Commission for Pharmaceutical Sector in this area. An inquiry by the Commission in 2008 analysed the abuses to the patent system by pharmaceutical companies. According to the inquiry, for the period of 2000-2007, a delay of seven months in market entry for generic medicines cost the EU health system three billion Euros. Article 9 of the draft DCFTA would allegedly deny market entry to generic medicines for a maximum of eleven years, which would result in tremendous costs to the health system of the Republic of Moldova.

I have addressed a separate communication to the Government of Moldova about this situation that has been brought to my attention.

In view of the urgency of the matter, I would appreciate a response within sixty days on the initial steps taken by your institution 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 information if a human rights impact assessment of the negotiated DFCTA has been undertaken. If so, what is the result of the assessment? If not, why has it not been carried out?

3. Please provide details of any actions taken, before and during negotiations on DFCTA, to address any potential negative impact of the agreement on the right of access to medicines by everyone in the Republic of Moldova, especially vulnerable or marginalized groups.

I undertake to ensure that the response of the Commission 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, Mr. Fule, 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