NATIONS UNIES
HAUT COMMISSARIAT DES NATIONS UNIES AUX DROITS DE L'HOMME

PROCEDURES SPECIALES DU 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)
OTH 6/2013

1 July 2013

Dear Mr. De Gucht,

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 thank for your letter of 24 October 2012, in which you replied to concerns raised in my letter of 21 August 2012 regarding the negotiations under article 9 of the Deep and Comprehensive Free Trade Agreement (DCFTA) between the European Union and the Republic of Moldova and its potential impact on the affordability of essential medicines for poorer sections of the population in the Republic of Moldova.

While I take note of the listed European Union initiatives, your Excellency's response does not fully address concerns communicated to me about the steps taken to address any potentially negative impact of the DCFTA negotiations on the continued enjoyment of the right to health by the population in Moldova.

Your letter referred to the independent study, commissioned by the European Commission, on "Trade Sustainability Impact Assessment in support of a DCFTA" (TSIA), which intended to assess the human rights impact of the DCFTA in Georgia and Moldova. In this respect, it was stated that the study did not identify any "specific negative impacts of the agreement on access to medicines or suggest any particular flanking measures". However, I would like to refer your Excellency's attention to the portion of the study, which admits that the TSIA has not conducted any assessment of the human rights impact of the DCFTA on any specific sector in its report, since "no specific sectors" had been decided under the DCFTA at the time of the study (p. B64).

Furthermore, your letter notes TSIA's expectation of an overall "positive effect on human rights in the Republic of Moldova as a result of the DCFTA". In this regard, I would like to draw your Excellency's attention to pages B67 and B68 of the study that states that the "overall human rights effects of the DCFTA has positive *and* negative elements." It should also be pointed out that the positive impact, as assessed by TSIA, is

that there would be a rise in national income levels and access to third-country markets, while also encompassing "broader human rights values". There is no clarity on what "values" recognized under international human rights are envisaged to be covered within the DCFTA or how these values are to be respected, protected and fulfilled under the right to health framework. Importantly, the letter omits to mention that TSIA clearly states that the DCFTA the negative effect of the DCFTA is to increase income inequality and a greater loss of disposable income for the poorest parts of the population (p. B68). In this respect, it is important to highlight the following elements of the current situation in Moldova.

According to the latest figures by the World Bank, 21.9 per cent of the Moldovan population lives below the national poverty line,[1] contrary to the 2-3 per cent that has been mentioned in TSIA study (p. B11). Public and private expenditure sourced through insurance covers only 27.9 per cent of the total drug expenditure in the Republic of Moldova. Expenditure on medicines comprises 79 per cent of the total out-of-pocket expenditure on health, making Moldovan population more vulnerable to the lack of financial protection.[2] WHO study on health financing in Moldova reveals that almost all of those seeking inpatient treatment at hospitals paid for medicines out-of-pocket.[3] Despite efforts to reform the public health system through the introduction of universal healthcare coverage, high levels of catastrophic spending by households driven specifically by outpatient medicines still persist.[4]

Moreover, the human rights impact assessments under the TSIA was carried out in the absence of any context to the sectors to which they relate and therefore the conclusions are founded on unsubstantiated grounds. It places the entire onus of mitigating the potential negative effects of the DCFTA upon the Moldovan authorities in the context of the Association Agreement and also in the extent to which Moldova has ratified core human rights treaties, which according to its own assessment later in the study is unsatisfactory (pp. B66-B67). The last section of Table 3.7 states that the right to participation in the conduct of public affairs in the negotiation and implementation of the DCFTA in the country is "undetermined", that "more efficiency" is one of the goals of the DCFTA, and that "all other considerations might play 2nd fiddle". It also shows that the enforcement of the DCFTA would be stronger than the enforcement of human rights law as the DCFTA has a "higher priority" (Table 3.7). Your Excellency's assurances to uphold human rights in the negotiation of the DCFTA are not supported by the conclusions found in the TSIA.

While it is well accepted that, as a WTO Member, the Republic of Moldova is required to fulfil its obligations to implement the TRIPS Agreement nationally, including

[1] See http://data.worldbank.org/country/moldova
[2] Stela Bivol and Viorel Solten, Negative Impact of Data Exclusivity on Access to Medicines, Health Monitor, 13 July 2012, p. 7. Available at www.pas.md/public/files/doc/express_analysis_1_2012_en.pdf
[3] Sergey Shishkin and Matthew Jowett, A review of health financing reforms in the Republic of Moldova, Health Financing Policy Paper 2012/1, WHO Regional Office for Europe, 2012, p. 25. Available at http://www.euro.who.int/en/what-we-do/health-topics/Health-systems/health-systems-financing/publications2/2008/20083-evaluation-of-moldovas-2004-health-financing-reform
[4]

the obligations under article 39(3), the submission by your Excellency that the article 39.3 requires protection for "undisclosed test and other data" is an incorrect reading of the provision. First, the reference to the obligation to protect "other data" is unclear as to its nature and scope. Second, article 39(3) protects only "undisclosed data" from "unfair commercial use", without conferring exclusive rights or period of market monopoly which the present article 9 of the DCFTA purports to do. Article 9 of the DCFTA relates to data exclusivity and not to the protection of undisclosed data, which are two distinct concepts. Data exclusivity is a TRIPS Plus provision, which creates market exclusivity, independent of patent status. Data exclusivity prevents the registration and marketing approval of generic medicines (under article 9 of the DCFTA this period would be for 8+2+1 years), by disallowing them the use of clinical trial data relied upon by the originator company even after the expiry of the patent term,[5] contrary to your letter's assertion (para.4, p. 2). Generic competition has been demonstrated to reduce the price of medicines in the HIV context.[6] A 2007 report by OXFAM, which studied the impact of data exclusivity provisions in the 2001 EU-Jordan FTA on prices of medicines in Jordan, showed that out of 103 medicines registered and launched in Jordan since 2001 at least 79 per cent did not have generic competition as a consequence of data exclusivity. As a result of the enforcement of data exclusivity by multinational companies with no generic competitor, there was an additional expenditure for medicines between USD 6.3 million to USD 22.04 million, which lead to increased prices for individuals as well as the public health system in Jordan.[7]

Your Excellency's letter puts forth an argument that a legal framework that strongly protects patents is required to spur innovation. However, evidence has shown that longer periods of data exclusivity (distinct from patents) have not resulted to better medicines. On the contrary, this has led to the proliferation of "me-too" medicines (structurally similar to already known medicines, with only minor differences), which in some countries account for 60 per cent of the new medicines in the market and increase public health expenditure on medicines.[8]

While the right to health framework relies on elements like availability, accessibility, acceptability and quality determined by conditions of adequate infrastructure, healthcare workers, and public procurement and distribution systems to ensure accessibility to medicines, as alluded to by your letter, the price of medicines is also crucial to ensuring economic access to medicines. The impact of data exclusivity on the price of medicines is more concerning especially in circumstances when out-of-pocket expenditure on medicines forms a significant part of the health expenditure of the population, who are not covered or have access to limited insurance coverage,

---

[5] All costs, no benefits: How TRIPS-Plus intellectual property rules in the US-Jordan FTA affect access to medicines, OXFAM Briefing paper, p. 8.Avaialble at http://policy-practice.oxfam.org.uk/publications/all-costs-no-benefits-how-trips-plus-intellectual-property-rules-in-the-us-jord-114080

[6] Overcoming Barriers to Access: The Issues, MSF. Available at http://www.msfaccess.org/content/overcoming-barriers-access-issues

[7] OXFAM Briefing Paper, p.23.

[8] Light DW, Lexchin J, Foreign Free riders and the high price of US medicines. BMJ. 2005; 331 (7522); 758-760.

There is now growing evidence of the adverse impacts of TRIPS Plus provisions like data exclusivity on the affordability of medicines, which infringes on the right to health of poorer populations.[9] The requirement of approximation of Moldova's intellectual property laws with European Union law as a condition for strengthening economic links seems to be more in favour of the European Union than Moldova. These include providing pharmaceutical companies based in the EU with stronger intellectual property protection through TRIPS plus provisions like data exclusivity and stringent enforcement standards for patent infringements if previous EU-negotiated FTAs are a standard to go by.

The European Union's efforts at promoting access to medicines through funding of the Global Fund to fight AIDS, TB and Malaria and the GAVI Alliance are well accepted. At the same time, however, concerns have been raised by several humanitarian organisations about the adverse impact of EU's policies on enforcing patent infringements through TRIPS Plus provisions negotiated through FTAs. If similar TRIPS Plus provisions are advocated by the EU under the DCFTA, then access to generic medicines may also become an issue. Given the allegedly non-transparent negotiation process of bilateral FTAs, at this stage information provided to the public regarding the DCFTA is insufficient to enable them to voice concerns. Regrettably, the TSIA did not involve the affected population of Moldova in the negotiations or the implementation of the DCFTA.

Although the European Union implemented the 2003 Decision on the Implementation of the Paragraph 6 of the Doha Declaration on the TRIPS Agreement into its laws to facilitate EU pharmaceutical companies to apply for licences to export to countries in need of medicines, there have been no compulsory licenses applied for under the EU mechanism so far. On the question of EU's adoption of rules for tiered pricing, evidence has shown that it has been used for only a few medicines and would not be affordable to patients who cannot afford even the marginal cost of manufacturing other than the risk of eroding high-income market segments due to external referencing.[10]

In light of the above and in my capacity as the United Nations Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, I would urge your Excellency to carry out a more substantial human rights impact assessment of the impact of data exclusivity on the affordability of medicines in the Republic of Moldova. It is my responsibility under the mandate provided to me by the Human Rights Council, to seek to clarify all cases brought to my attention. I undertake to ensure that the information received from your Excellency will be reflected in the report I submit to the Human Rights Council for its consideration.

Please accept, Mr. De Gucht, the assurances of my highest consideration.

[9] Ibid, note. 5

[10] Prashant Yadav, Differential Pricing for Pharmaceuticals: review of current knowledge: new findings and ideas for action, *DFID,* August 2010.

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