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Express Analysis:

Negative Impact of Data Exclusivity on Access to Medicines

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THE ISSUE

In the current negotiations for Deep and Comprehensive Free Trade Area Agreement, the European Union (EU) requires the Republic of Moldova to introduce in the national legislation *data exclusivity* as a new form of intellectual property protection. *Data exclusivity* would allow pharmaceutical companies to hold exclusive rights over their clinical test data for a defined period of time. This means that manufacturers of generic medicines would not refer to the clinical test results of the originator drug for a maximum period of 11 years (8+2+1) and would not be able to enter the market of the Republic of Moldova.

In essence, this measure ensures the exclusive right and market monopoly of originator drugs for a maximum of 11 years and the European Union promotes this measure to return initial investments that lead to discovering an innovative pharmaceutical entity. To support its position, the European Union brings several arguments that are discussed below in this document.

EU ARGUMENT No. 1: HIGHER PROTECTION LEADS TO MORE INVESTMENT

The General Directorate Trade (DG Trade) considers that it is only just that companies ask for exclusive rights regarding their clinical test data, and if there is not enough profit, big pharmaceutical companies would not invest in research and would not produce innovations. The DG Trade considers that the stronger the protection measures for intellectual property are, the more investment in new drug development.

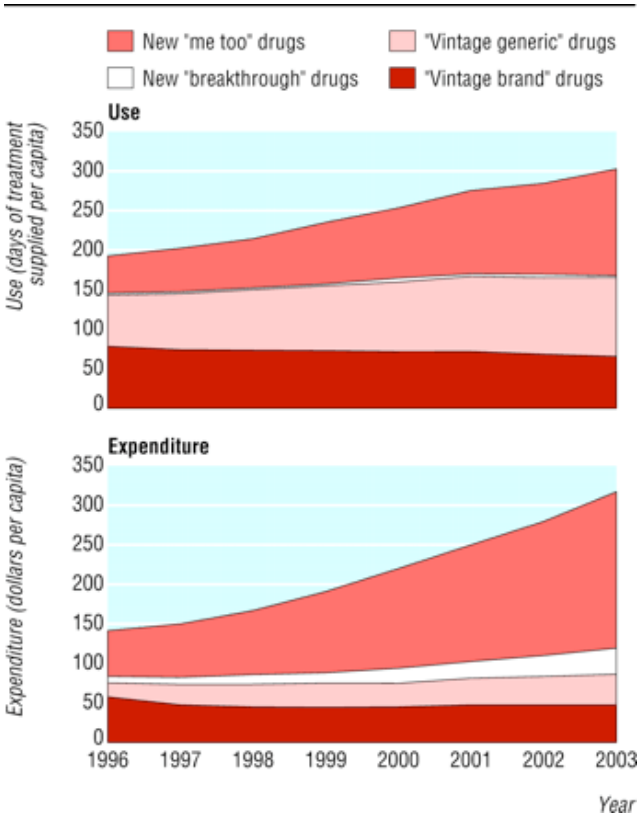
Based on an express analysis, the authors came to the conclusion that this does not happen in reality. **In fact, longer data exclusivity does not lead to better drugs**. Only 1.3 percent of pharmaceutical revenues go to discovering new drugs. Several independent reviews conclude that most new drugs offer few if any therapeutic advantages. "New" drugs in fact are old drugs and are known as "me-too" drugs. Government-protected prices through longer data exclusivity strengthen incentives for companies to develop more drugs of marginal benefit and these new drugs account for about 60 percent.[1]

A study conducted in Canada showed that the biggest share of expenditures in the Canadian health system belongs to "me-too" drugs, when a new ingredient is added to a known substance or a new therapeutic indication is found. There is a decreasing trend in expenditures for new pharmaceutical drugs and for generic drugs. As a result, **health expenditures for prescribed drugs are constantly increasing.**[2] The authors of this express analysis consider that a similar effect will occur in the Republic of Moldova if data exclusivity is adopted.

The figure below is extracted from the same study and it presents the use and the expenditures by the health system for prescribed drugs in Canada for years 1996-2003.[3] One can easily note that "me-too" drugs are increasingly used and more money is spent for this type, whereas use and expenditures for generic drugs is on decrease.

1 "Light DW, Lexchin J. Foreign free riders and the high price of US medicines. BMJ. 2005; 331(7522): 958–60.
2 Steven G Morgan Kenneth L Bassett, James M Wright, Robert G Evans, Morris L Barer, Patricia A Caetano, Charlyn D Black. "Breakthrough" drugs and growth in expenditure on prescription drugs in Canada. BMJ 2005;331:815
3 Ibid

In developing countries with little innovative capacity, as is the case of the Republic of Moldova, the benefits are limited, but the costs are significant.[4] *Data exclusivity* and other protection measures are **intended to protect the interests of big pharmaceutical companies**, to ensure them with profits for an 11-year period.



Data exclusivity is a means of maintaining artificially high prices, thereby restricting access to medicines for the citizens of the Republic of Moldova. Moreover, the World Health Organisation considers unethical to require generic manufacturers to conduct their own safety and efficacy trials with proven effective compounds. Clinical trials could expose patients from control groups to sub-optimal treatment. Proof of therapeutic equivalence should be sufficient.[5]

What EU does not mention are the **significant economic and health costs** as a result of the introduction of stricter intellectual property (IP) rules. **The effect of data exclusivity is to decrease access to medicines in the developing countries.** Non-communicable diseases affect equally both developed and developing countries, but there are significant differences in the capacity of the governments to respond to their burden. Most people in developing countries pay for medicines out-of-pocket, so even a slight price increase can mean that life-saving medicines are unaffordable. The EU member countries have special policies intended to reduce the drug prices and nearly all have introduced mechanisms to protect vulnerable groups from excessive out-of pocket payments. Many EU member countries employ price control strategies and generic prescription to ensure access of their populations.[6]

In parallel, concerned by the pharmaceutical marketing practices, in 2008 the EU has established a Commission for Pharmaceutical Sector Inquiry that analysed the abuses to the patent system by big pharmaceutical companies and the costs of these abuses for health systems and patients. One conclusion was that over the period 2000–2007, generic entry of a large number of medicines was delayed by up to seven months each, costing Europe three billion euros. The same reports have described a variety of other strategies used by "big pharma" to extend commercial life of their products and to delay market entry of generics. [7' 8]

4 Charles Clift. CHAPTER 4.9. Data Protection and Data Exclusivity in Pharmaceuticals and Agrochemicals. http://www.iphandbook.org/handbook/ch04/p09/ (Accessed July 9 2012)
5 WHO (2006). Briefing note access to medicines. Data exclusivity and other TRIPS-plus measures. http://www.searo.who.int/LinkFiles/Global_Trade_and_Health_GTH_No3.pdf (Accessed July 9 2012)
6 OXFAM (2009). Trading Away Access to Medicines. How the European Union's trade agenda has taken a wrong turn. http://www.oxfam.org/en/policy/trading-away-access-medicines (Accessed July 9 2012)
7 Ibid

Generic products are on average 40% cheaper two years after market entry compared to the originator drugs. Competition by generic products thus results in substantially lower prices for consumers.

Another example of estimating the economic effects of these IP policies comes from the experience of Latin American countries. Several countries that were in the negotiation process of free trade agreements with the EU have conducted studies to estimate the economic costs had EU conditions the stricter IP regulations been adopted. Columbia concluded that by 2020 the country would reach a level of market monopoly of approximately 63% due to the combined effect of patent and test data protection and the national generic industry could lose up to 57% of the value of its current market share. These measures would result in an approximate **40% increase in the price index for medicines and by 2020, a 919 million dollar increase in spending on medicines, which is equivalent to health-care expenditures for 5.2 million people enrolled as contributors in the social security system that year.** If expenditures are not increased, there could be a 40% reduction in consumption with consequences for access to medicines, particularly for low income people and families that cannot afford the higher costs.[9] Similarly, in Peru**, a 10-year test data exclusivity period, would lead to an increase of more than 300 million USD in medicines' expenditure in 2025**.[10]

In Ukraine, where a 6-year data exclusivity period has been introduced as an additional measure in its negotiations with the World Trade Organisation (WTO), the market authorization for the generic version for three antiretroviral and hypertensive drugs has been discontinued in 2010 and market entry for several antiretroviral drugs used for treating HIV/AIDS has been blocked. Currently there are five lawsuits related to drug registration for cancer treatment and one antibiotic. The price for antiretroviral drugs has already significantly increased.[11]

EU ARGUMENT No. 2: THE ARTICLE 39.3 OF THE TRIPS AGREEMENT IMPLIES DATA EXCLUSIVITY

The interpretation of the article 39.3 of the TRIPS Agreement is equivocal and ambiguous (see Annex 1). On one hand, the European Union supports the Doha Declaration regarding flexibilities around intellectual property and public health and considers that it does not ask for provisions that would limit access to medicines. On the other hand, the EU interpretation to the article 39.3 (which requires WTO members to non-disclose data and protect against unfair commercial use) in a much stricter way than is provided by this article. EU interprets this article as limiting the right of the generic competitor not only to access data of the patent holder, but also **to make reference to this dat**a (known as *non-reliance*).

First, **the article 39.3 of the TRIPS agreement does not ask for data exclusivity and additional data protection**. This article only asks for data non-disclosure and unfair commercial use**. The EU itself has shown its ambiguous attitude when it recognized that**... *"It must be admitted that the*

8 Antitrust - sector inquiry into pharmaceuticals (IP/08/49).
http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/08/20&format=HTML&aged=0&language=EN&guiLanguage=en (Accessed July 9 2012)
9 Gamba MEC (2006). Intellectual Property in the FTA: Impacts on pharmaceutical spending and access to meidinces in Colombia. http://www.ifarma.org/web/wp-content/uploads/2009/02/tlc_colombia_ingles1.pdf (Accessed 9 July 2012)
10 IFARMA HAI Europe (2009). Impact of the EU-Andean Trade Agreements on Access to Medicines in Peru. http://www.haiweb.org/11112009/ReportIFARMAImpactStudyPeru%28EN%29.pdf (Accessed 9 July 2012)
11 Kontantinov B. Data exclusivity and possible impact on access to treatment. Presentation in the meeting of TRIPS-plus provisions and their effect on access to medicines, Chisinau, July 11, 2012

following of Article 39.3 does not, from a prima facie reading, appear to impose data exclusivity during a certain period of time. This lack of clarity is the obvious result of a difficult negotiation process where divergences of views arose between developing and industrialized countries as to the necessity of EC/U.S. like type of data protection as well as among industrialized countries on the length of the data exclusivity period".[12] EU's interpretation regarding additional data protection and data exclusivity is a TRIPS-plus measure. [13]

Secondly, the **European Parliament has asked openly the Council to not negotiate TRIPS-plus measures in bilateral agreements**. In its resolution it says**:** "*Calls on the Council to meet its commitments to the Doha Declaration 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,*** *patent extensions and limitation of grounds of compulsory licences, within the framework of the EPA negotiations with the ACP countries and other future bilateral and regional agreements with developing countries."*[14]

The official position of DG Trade regarding intellectual property, as extracted from the official site, mentions: "*Access to medicines is an issue for which IPR aspects are particularly relevant. In this context, the European Union is committed to the Doha Declaration on TRIPS and Public Health and has consistently led efforts to facilitate access to medicines in developing countries,* ***and to strike the right balance between the IP rights of pharmaceutical companies and the need to ensure that medicines are available for populations in need in the developing world****. With regard to the free trade agreement (FTA) under negotiation with India, for instance, the EU fully acknowledges the right and capacity of this country to manufacture and export medicines to other developing countries facing public health problems, and does not propose IPR provisions which would restrict this possibility*."[15] This position is different from the one expressed currently in negotiations with Moldova.

Thirdly, **there is incoherence within EU structures, where its trade policies are not aligned to development objectives**. The EU's IP policies promoted by DG Trade undermine the efforts of other Directorates within the European Commission, such as DG Development, and the efforts of EU Member States at a national level that promote access to health care in developing countries. These policies favour the EU's commercial interests over health of those living in poor countries. They also undermine the obligations undertaken by the EC and Member States when they committed themselves to reaching the MDGs, the Doha Declaration on TRIPS and Public Health, and the WHO Global Strategy and Plan of Action. The EU requests for stricter IP rules exceed even the US requirements that impose countries within free trade bilateral agreements a data exclusivity period of only five years. [16]

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12 EU (2001)cited in WHO 2002. Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the Trips Agreement. http://apps.who.int/medicinedocs/en/d/Jh3009ae/ (Accessed 9 July 2012)
13 UNDP, UNAIDS (2012). Issue Brief. The potential impact of free trade agreements on public health. http://www.undp.org/content/undp/en/home/librarypage/hiv-aids/issue-brief--the-potential-impact-of-free-trade-agreements-on-pu/ (Accessed 9 July 2012)
14 European Parliament resolution of 12 July 2007 on the TRIPS Agreement and access to medicines. http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P6-TA-2007-0353+0+DOC+XML+V0//EN (Accessed 9 July 2012)
15 European Commission, Trade website. http://ec.europa.eu/trade/creating-opportunities/trade-topics/intellectual-property/ (accessed 9 July 2012)
16 OXFAM (2009). Trading Away Access to Medicines. How the European Union's trade agenda has taken a wrong turn. http://www.oxfam.org/en/policy/trading-away-access-medicines (Accessed 9 July 2012)

Fourthly, **the EU has already shown flexibility when negotiating bilateral FTAs with other developing countries in both general framework, and the length of data exclusivity.** EU started negotiations with Bolivia, Colombia, Ecuador and Peru in 2007. The IP Chapter turned to be most controversial and difficult sections of negotiations, because of concerns about access to medicines. Ecuador and Bolivia left the negotiation due in large part to concerns that strict IP rules would restrict access to medicines. The two countries staying in negotiations have brought evidence on economic impact and have obtained data exclusivity of 5 years, the same as the one signed under USA FTA.[17] **Even EU member countries have different data exclusivity terms, some managing to limit to three years and some to six years.**

One of the most recent controversial cases is the negotiation of the EU-India bilateral agreement, where India opposes the IP chapter and data exclusivity clause, since 90% of all generic medicines are produced in India and this would limit severely access to generics in the whole world. As a result, **Karel de Gucht in his letter showed a flexible position in negotiations with India: "*...the negotiations are still ongoing on this issue, but let me be very clear that we are ready to show the necessary flexibility here and fully take into account the specificities of the Indian legal system, the policy developments on this issue within India, its developing country status and the role it plays with regard to production of essential generics for the developing world*".[18]**

POTENTIAL IMPACT ON THE REPUBLIC OF MOLDOVA

The Republic of Moldova is a country where health expenditures for pharmaceuticals are already high and exceed the regional prices several times. Health expenditures from public and health insurance sources for pharmaceuticals cover only 27.9% from total drug expenditure, and most part of drug expenditures is paid directly by the population.[19] Drug expenditures represent 70% of out-of-pocket health expenditures in a household and are the main factor that reduces financial protection of the citizens when they access health services.[20] A comparative study conducted in eight CIS countries has shown that the main reason for two thirds (63.9%) of Moldovans who did not seek health care when they felt it was justified was the cost of drugs and health services.[21] Given this alarming situation, the Government of the Republic of Moldova has expressed its concern about its pharmaceutical market and regulation and has set as a priority medicines price reduction and decrease of financial burden on its citizens. **Introduction of *data exclusivity* would be counterproductive to this effort.**

Another area where the effect of adopting data exclusivity will have an immediate effect is HIV/AIDS treatment. At the moment, all antiretroviral drugs necessary for HIV/AIDS treatment are procured through external sources, without being registered in the country, and only one original antiretroviral drug has already been registered. When the Republic of Moldova takes over drug procurement through public procurement mechanisms and, if data exclusivity is adopted, the costs

[17] HAI Europe (2011). European Union& Andean Community Trade Agreements, Intellectual Property and Public Health. http://haieurope.org/wp-content/uploads/2012/01/Sep-2011-European-Union-Andean-Community-Trade-Agreements-Intellectual-Property-Public-Health.pdf (Accessed 9 July 2012)

18 Karel de Gucht, Member of the European Commission. Letter addressed to Tido von Shoen-Angerer, Director of Campaign for Essential Medicines, Medecins sans Frontieres. Bruxelles, 25.05.2010

19 WHO 2012. Health for All database. (Accessed 9 July 2012)

20 Negruta A (2012). Health expenditures and catastrophic expenditures: data from household budget survey. Unpublished report..

21 Balabanova, D., Roberts, B., Richardson, E., Haerpfer, C. & McKee, M. (2012). 'Health Care Reform in the Former Soviet Union: Beyond the Transition'. *HEALTH SERVICES RESEARCH*, vol 47, no. 2, pp. 840-864.

of ARV treatment will significantly increase at least several times, and the access to generics that are currently used for at least 2,000 patients will be denied for at least 10 years. This will lead to treatment interruptions, changes in the drug regimens and premature deaths. At the same time, there is a need for studies to calculate exactly the economic costs of introducing this policy.

RECOMMENDATIONS

1. Given the anticipated significant economic and social costs that are well documented by other countries that have been in the process of negotiation bilateral trade agreements with the EU, we call both the Government of the Republic of Moldova and the European Union to show sensibility, **support to public interest and prioritization of the right to health of citizens of the Republic of Moldova**. The negotiation of intellectual property rights has to exclude parties that have a conflict of interest in promoting public interest.

2. To ensure **gradually** the harmonization of the legislation of the Republic of Moldova to that of EU and to support the position that data exclusivity enters into force only when Moldova becomes an EU member. The official position of the Republic of Moldova should be in line with Doha Declaration and limit to non-disclosure and unfair commercial use, while adhering to the EU interpretation that are TRIPS-plus (including data exclusivity) should be postponed until becoming a EU member country.

3. In order to estimate in-depth the impact of this public policy, it is necessary to conduct an ex-ante analysis by an independent institution, without conflict of interests and not with EU's financial of technical support.

ANNEX 1: TRIPS, TRIPS PLUS AND DOHA DECLARATION

The Agreement on Trade-Related Aspects of Intellectual Property Rights (or TRIPS Agreement) set the standards for intellectual property protection in the world today. It came into force on 1 January 1995 and is binding on all members of the World Trade Organization (WTO).

TRIPS: A ONE-SIZE-FITS-ALL APPROACH

The TRIPS Agreement sets minimum standards in the international rules governing patents, including on medicines. Countries that are members of the WTO agree to certain common standards in the way they enact and implement their patent laws. These standards include, amongst others, that patents be given for a minimum of 20 years; that patents may be given both for products and processes; and that pharmaceutical test data be protected against 'unfair commercial use'.

But the question of what deserves to be patented is left for countries to determine. The Agreement only says that patents should be granted for new, inventive and useful inventions - but it does not define these terms. Deciding whether a new formulation (producing a pill version of a drug that formerly came as a powder, for instance) or a new combination (combining two or more existing molecules into a new pill) deserves a new twenty-year patent for example is a prerogative of countries, and is not determined by the WTO texts. Countries should therefore determine what kind of inventions deserves patents in the area of pharmaceuticals, in light of their own social and economic conditions. Some governments, such as Brazil, Thailand or India, have done precisely that. In today's world, for many patients, that decision can be a question of life or death.

In other words, though there is no such thing as a single international patent law, TRIPS represents a harmonisation of patent laws. The industry had been pushing for this kind of move for decades. It's a one-size-fits-all policy that aims at extending the stricter patenting laws previously used in industrialised countries to developing countries, regardless of their radically different social and economic conditions.

Developing country members of the WTO generally had until the beginning of 2000 to implement TRIPS. Some countries were given a longer transition period – those like India that did not grant patents on pharmaceutical products were given until 2005, and least-developed countries were initially given until 2006.

THE DOHA DECLARATION: RESTORING THE BALANCE

Implementation of the TRIPS Agreement's intellectual property standards is having a considerable impact on access to medicines and public health. By limiting competition and local manufacturing, the danger is that TRIPS extends high drug prices and worsens the access to medicines crisis.

With TRIPS, life-saving medicines are considered in the same vein as mere consumer goods and the devastating impact of high prices is mostly ignored. The balance between the private interests of the patent holder and the larger interests of society is severely skewed.

It didn't take long for the issue to come to a head. In 2001, at the annual ministerial meeting of the WTO in Doha, Qatar, countries agreed to redress that imbalance, and firmly restated the primacy of health over commercial interests. The Doha Declaration reaffirmed countries' right to use TRIPS

safeguards such as compulsory licences or parallel importation to overcome patent barriers to promote access to medicines, and guided countries in their use. One final significant achievement of Doha was to extend the deadline by which the least developed countries had to grant and enforce pharmaceutical patents, from 2006 to 2016. This deadline needs to be further extended or they will face the same difficulties that other developing countries already contend with in accessing medicines.

TRIPS PLUS: GOING EVEN FURTHER THAN TRIPS

Despite the Doha Declaration, in recent years, many developing countries have been coming under pressure to enact or implement even tougher or more restrictive conditions in their patent laws than are required by the TRIPS Agreement – these are known as 'TRIPS plus' provisions. Countries are by no means obliged by international law to do this, but many, such as Brazil, China or Central American states have had no choice but to adopt these, as part of trade agreements with the United States or the European Union. These have a disastrous impact on access to medicines.

Common examples of TRIPS plus provisions include extending the term of a patent longer than the twenty-year minimum, or introducing provisions that limit the use of compulsory licences or that restrict generic competition.

One of these provisions is known as data exclusivity. This refers to exclusive rights, granted over the pharmaceutical test data submitted by companies to drug regulatory authorities for obtain market authorisation. It means that information concerning a drug's safety and efficacy is kept confidential for a period of, say, five or ten years.

If a generic manufacturer wants to register a drug in that country, it is not allowed simply to show that their product is therapeutically equivalent to the originator product. Instead, it must either sit out the exclusivity period, or take the route of repeating lengthy clinical trials to demonstrate the safety and efficacy of the drug – trials that have already been undertaken. This happens even when the originator product is not patented. In other words, data exclusivity is a backdoor way of preventing competition, so that even when a medicine is not protected by a patent, a pharmaceutical company will receive a minimum period of market monopoly when artificially high prices can be charged.

Data exclusivity and other TRIPS plus provisions are frequently pushed as a part of free trade agreements between developed and developing countries.

(Annex 1: Full text taken from Medecins Sans Frontieres Access Campaign: TRIPS, TRIPS plus and Doha, July 2011, http://www.msfaccess.org/content/trips-trips-plus-and-doha)