ACCESS TO HIV TREATMENT, OTHER ESSENTIAL MEDICINES AND INTELLECTUAL PROPERTY

National Consultations

Republic of Moldova

18-19 November 2014

Upon request by the Ministry of Health of the Republic of Moldova UNDP, in collaboration with WHO, organized National Consultations on access to HIV treatment and other essential medicines in the context of the recently concluded Association Agreement with the EU and expected amendments in national intellectual property legislation and related laws. The goal of the Consultations was to examine the likely impact on access to treatment for people living with HIV and co-infections in Moldova and to explore measures that could be employed by Moldova to meet its public health obligation to ensure access to affordable medicines.

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List of Acronyms and Abbreviations

AA	Association Agreement
AGEPI	State Agency on Intellectual Property of the Republic of Moldova
AIDS	acquired immune deficiency syndrome
ART	anti-retroviral therapy
ARV	anti-retroviral (medicine)
CD4	cluster of differentiation 4 (glycoprotein)
COBI	cobicistat
DCFTA	Deep and Comprehensive Free Trade Area
EECA	Eastern Europe and Central Asia
EFTA	European Free Trade Association
EU	European Union
EVG (QUAD)	elvitegravir/cobicistat/emtricitabine/tenofovir
FTA	free trade agreement
FTC	emtricitabine
GARPR	Global AIDS Response Progress Report
GFATM (Global Fund)	Global Fund to fight AIDS, Tuberculosis and Malaria
GPRM	Global Price Reporting Mechanism
HIV	human immunodeficiency virus
IFARMA	IFARMA Foundation
LPV/RTV	lopinavir/ritonavir
MENA	Middle East and North Africa
MSM	men who have sex with men
PID	people who inject drugs
PLHIV	people living with HIV
PMCT	prevention of mother to child transmission
SW	sex workers
Swissmedic	Swiss Agency for Therapeutic Products
TDF	tenofovir disoproxil fumarate
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights (WTO)
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNDP	United Nations Development Programme
WHO	World Health Organization
WTO	World Trade Organization

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National Consultation on
Access to HIV Treatment and other Essential Medicines and Intellectual Property

18 - 19 November 2014

Republic of Moldova, Chisinau
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127, 31 August 1989 Str.

Upon request by the Ministry of Health of the Republic of Moldova (Letter No. 11-4/718 from 29 August 2014), UNDP, in collaboration with WHO, organized National Consultations on access to HIV treatment and other essential medicines in the context of a recently concluded Association Agreement with the EU and expected amendments in Moldova's national intellectual property legislation and related laws. The goal of the consultations was to examine the likely impact of these developments on access to treatment for people living with HIV and co-infections in Moldova and to explore measures available in intellectual property related legislation that could be employed by Moldova to meet its obligation to ensure access to affordable medicines (see Agenda – Annex I). The meeting was attended by 20 people representing the different relevant national and international agencies, including the Ministry of Health, Ministry of Foreign Affairs, State Intellectual Property Agency, National Parliament, Medicines Agency, civil society, UNAIDS, UNDP and WHO (see List of Participants – Annex II).

Objectives of the Consultation

- Review the current situation with respect to HIV treatment (registration, prices, patent situation).
- Review the proposed changes in national legislation required to implement the EU Accession Agreement taking into account obligations and flexibilities present in the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and identify the possible public health implications.
- Discuss experiences of other countries in the EECA region and beyond and share good practice examples of public health sensitive provisions and policies.
- Identify the opportunities to mitigate potential risks for access to medicines in the context of intellectual property protection and enforcement.
- Develop recommendations for the adoption of measures to mitigate the potentially negative impact of TRIPS-plus commitments in Moldova.

The presentations focused on the:

- current situation with respect to access to and cost of HIV treatment and the legal situation with respect to intellectual property protection, including Moldova's obligations under the WTO TRIPS Agreement and the Association Agreement (AA) with the EU;
- experience with free trade agreements in Ukraine and in other countries and regions;
- availability and affordability of essential medicines in the Republic of Moldova; and
- possible models of enhanced national cooperation in the area of public health and intellectual property.

Access to and cost of HIV treatment

Anti-retroviral therapy (ART) use has been scaled-up across the WHO European Region. Although no low- or middle-income country has yet achieved the 2015 European estimated coverage target of

80%, the number of people receiving ART increased considerably. Hence, estimated ART coverage in the east increased from 23% (129,000) in 2010 to 35% in 2012 (199,000). In the west, ART estimated coverage was high (560,000), and most countries had achieved or were expected to achieve the 80% ART estimated coverage target by 2015.

WHO Response in Europe is guided by two key documents: (i) European Action Plan on HIV/AIDS 2012-2015; and (ii) 2013 WHO Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection (Recommendations for a Public Health approach). Pursuant to these strategic papers, the national protocols for HIV treatment and care in adults and adolescents were updated. Notably, it endorsed a shift to 500 CD4 count to initiate treatment, and endorsed the approach of lifelong ART for all pregnant and breastfeeding women with HIV regardless of CD4 count or clinical status for prevention of mother to child transmission. ART in prisons and Transnistria region still largely draws upon funding from the Global Fund to fight AIDS, Tuberculosis and Malaria (GFATM).

In 2014, in Moldova of the nearly 15,000 estimated PLHIV, 8,557 have been diagnosed, about 5,200 are actively followed up. Almost 2,500 are in ART and roughly 1,700 have undetectable viral load.[1] This is indicative of the need to increase access to HIV testing, enrolment into HIV treatment and care programme in Moldova. Retention in treatment has been relatively consistent (81.2% after 12 months vs. 78.5% at 24 months vs. 74.2% at 60 months).

Based on the latest Global AIDS Response Progress Report (GARPR) and ART mapping exercise conducted in 2014, most of ART patients in Moldova (88.1%) get first-line regimens (10 options, price averaging US$ 202 per patient a year, with another 11.1% getting second-line drugs (seven options, price averaging US$ 807 per patient a year). Patients on salvage regimens accounted for less than 1% as of 2014 (eight treatment options).

Over the past years, Moldova has procured generic fixed-dosed combinations as first-line treatment at low prices (around US$ 180 per patient per year). The situation is comparable for most of the second-line treatments with the exception of lopinavir + ritonavir which is sourced at significantly higher prices from the originator company. With respect to third line treatment, Moldova procured darunavir for 18 patients overall from the originator company at a price of more than US$ 9,000.[2]

Moldova is included in all license agreements signed by the Medicines Patent Pool on tenofovir alafenamide, tenofovir, emtricitabine, cobicistat, elvitegravir, and the combination of TDF, FTC, COBI, and EVG (QUAD), pediatric abacavir, dolutegravir (adult and pediatric) and atazanavir as well as in the license agreements on rilpivirine and relevant combinations (with tenofovir, lamivudine, emtricitabine). Thus, Moldova will be able to procure these ARVs from mainly Indian generic producers.[3]

Moldova is part of several UNAIDS global and regional initiatives, which are promoting the intensification of National HIV responses efforts in order to reverse the epidemics by 2020 as mid-term and by 2030 as long-term targets. Eastern Europe and Central Asia region (EECA) is one of the few regions where HIV incidence and mortality are still increasing.

[1] UNAIDS, Republic of Moldova, Progress Report HIV, January 2012 – December 2013, Chisinau 2014.
[2] Increasing access to HIV treatment in middle-income countries: Key data on prices, regulatory status, tariffs and the intellectual property situation, WHO 2013 as well as the data in the WHO Global Price Reporting Mechanism for HIV, tuberculosis and malaria: http://apps.who.int/hiv/amds/price/hdd/
[3] See: www.medicinespatentpool.org/current-licences/

The number of registered new cases in Moldova was stable during the last five years – around 700 per year. The last integrated bio-behavioral research of HIV prevalence among key populations realized in the period 2012-2013 shows a decrease only in HIV prevalence among people who inject drugs in Chisinau, from 16.4% in 2009 to 8.5% in 2012, with HIV prevalence in Balti remaining at the level of about 40% and remaining at 20% in Tiraspol. Progress was not registered for the other key populations, like HIV prevalence in sex workers (weighted value for the right bank 7.3% in 2013 from 6.7% in 2010) and men having sex with men (weighted value 8.2% in 2013 from 0.2% in 2010). The coverage with prevention services of key populations remains also far from the recommended 60% (rising up to about 45% in people who inject drugs). For treatment, the last GARPR reported 16.8% coverage of those estimated in need according to the 2013 WHO Guidelines criteria for ART, and about 33% coverage according to the 2010 WHO Guidelines criteria.[4] All these impact and outcome results exemplify the need for Moldova to be part of the global and regional initiatives, like retargeting within the 90-90-90 initiative.[5] The 90-90-90 initiative encourages governments to create and implement policies and interventions aimed at diagnosing 90% of estimated people with HIV, to put 90% of those diagnosed on treatment, and for 90% of those in treatment to be virally suppressed. Within the new funding model application to Global Fund made in mid-2014, (covering the period 2015-2017), Moldova has fixed the ambitious target to almost double the number of HIV patients to be enrolled in treatment compared to the baseline of 2013. This will increase the financial resources required to ensure treatment.

By November 2014, Moldova succeeded to collect and analyze the epidemiological, demographic and economic data to provide the first preliminary results for an HIV allocative efficiency study. HIV allocative efficiency studies are generally trying to answer the question "How can HIV funding be optimally allocated to the combination of HIV response interventions that will yield the highest impact in the shortest period of time?"

The results showed, for example, that in an optimized scenario to decrease HIV incidence and mortality by 2020 using the same amount of finance as in 2013, 70% of resources have to be invested into treatment. The final data, to be available in the first quarter of 2015, will provide more information and evidence to be used for the programmatic and investment goals.

To achieve the goal of universal access to treatment, it is important to optimize treatment regimens, ensure reasonable and low prices of the medicines, ensure the good procurement and supply management of the drugs, and a smooth taking over of the costs and the procurement currently assured by the Global Fund by the national government.

Legal situation with respect to intellectual property protection, including Moldova's obligations under the WTO TRIPS Agreement and the EU Association Agreement

The Republic of Moldova has been a member of WTO since 26 July 2001 and thus is bound to implement the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

[4] See: UNAIDS, Republic of Moldova, Progress Report HIV, January 2012 – December 2013, Chisinau 2014.
[5] "By 2020, 90% of all people living with HIV will know their HIV status. By 2020, 90% of all people with diagnosed HIV infection will receive sustained antiretroviral therapy. By 2020, 90% of all people receiving antiretroviral therapy will have viral suppression", http://www.unaids.org/en/resources/documents/2014/90-90-90

The WTO Accession Protocol in the area of health-related intellectual property rights contains no additional obligations that go beyond the requirements of the TRIPS Agreement.

The current Moldovan Law on the Protection of Inventions (No. 50-XVI of March 7, 2008, as amended) provides for patent protection of inventions in the area of pharmaceuticals in line with the TRIPS Agreement. Patents are registered by the State Agency on Intellectual Property of the Republic of Moldova (AGEPI). AGEPI carries out substantive patent examinations on request, including by a third party (article 46).

In October 2013, the AGEPI and the European Patent Office signed a validation agreement that, when finally approved, will allow European patent applications and patents to take legal effect in Moldova without additional examination.[6] European patents will consequently have the same legal effect as Moldovan patents, and be subject to Moldovan law. At present, it appears that the Agreement has not yet been approved by the Moldovan Parliament and implementing legislation has not been passed. If ratified it is likely to lead to an increasing number of (pharmaceutical) patents in Moldova as applicants at the European Patent Office can choose to extend the geographic scope to Moldova.

Moldova has introduced a number of the public health related TRIPS flexibilities that WTO Members can use to facilitate access to affordable medicines, but not all.

Pre-grant flexibilities

1) Article 27 of the TRIPS Agreement allows WTO Members to exclude “diagnostic, therapeutic and surgical methods for the treatment of humans or animals” from patentability. This exemption is not included in the Moldovan legislation.

2) Moldova’s patent law does provide for the opportunity to file observations by third parties in the patent granting process: "following the publication of the patent application, any third party may (…) present observations concerning the patentability of the invention" (Article 89, see also §§ 202 - 207 Regulations on the Procedure of Filing and Examination of a Patent Application and of Grant of a Patent). This procedure can help to improve the quality of patents.

3) Although this is not required by the TRIPS Agreement, Moldova’s Regulations on the Procedure of Filing and Examination of a Patent Application and of Grant of a Patent allow for the patentability of the first medical use of an earlier known substance for pharmaceutical purposes and the second medical use of a known pharmaceutical substance for other purposes/results. For instance, zidovudine was initially developed as a medicine to treat cancer (first medical use) and later became one of the first anti-viral medicines used to treat HIV patients (second medical use).

4) The definition of patentability criteria does not contain any restrictions for the patentabiliy of variations or different forms of known pharmaceutical substances.

5) The Law on the Protection of Inventions provides for supplementary protection certificates for primary patents on medicinal or phytopharmaceutical products (Article 69). The protection period is the period covered between date of filing of the patent application and date of issuance of the first market authorization of the product minus five years (Article 69(2)). AGEPI stated that under this provision so far no certificates have been granted for

[6] See: www.epo.org/news-issues/news/2013/20131021.html

pharmaceuticals in Moldova. Once Article 314 of the DCFTA is in force, it will oblige Moldova to provide such certificates.

Post-grant flexibilities

1) The general point was made that all public health related flexibilities found in the TRIPS Agreement should be read in conjunction with the overarching principles of TRIPS. These include Article 7 which notes that *"[t]he protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology knowledge and in a manner conducive to social and economic welfare, and to balance of rights and obligations"* and Article 8 which enables WTO Members to *"adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development".*

2) It was noted that at present, Moldova's patent law, while allowing for some exceptions as envisaged under Article 30 of TRIPS such as experimental use, individual use and public non-commercial use does not provide for a Bolar exception. A Bolar exception usually exempts activities aimed at preparing the request for market authorization and the production facilities for a generic product from being a patent infringement. The Bolar exception can be an important enabler of generic competition and should thus be included.

3) Moldova's patent law contains a compulsory licensing provision as provided for under Article 31 of TRIPS. However, the opportunity exists for the procedure to be amended from a public health perspective. Possible amendments that could streamline the issuance of compulsory licenses in Moldova include:

    a. Removing provisions that can result in compulsory licenses being delayed through the use of litigation, for instance, by setting clear timelines for negotiations between voluntary license applicants and patent holders;
    b. Delegating the authority to issue compulsory licenses and declaring government use to administrative bodies; and
    c. Widening the list of interested parties who are eligible to file an application for a compulsory license to be issued.

4) Parallel importation is an important flexibilty as originator companies often sell the same medicine at significantly different prices depending on the market. At present, Article 23 (1) of the Law of Moldova on Inventions only provides for national exhaustion of rights. Moldova is unable to provide for the international exhaustion of rights because of its commitments under Article 279 of the DCFTA, but retains the flexibility to provide for the regional exhaustion of rights. Under regional exhaustion Moldova could import patented medicines from other European countries if there are other EU countries that pay lower prices for these medicines.

5) There may be unexplored opportunities to regulate anti-competitive behaviour by both originator and generic pharmaceutical companies through the use of competition law in Moldova. Compulsory licenses issued on the grounds of anti-competitive conduct contain fewer requirements including a waiver of Article 31(b) which requires that the proposed user should have attempted to obtain authorization from the right holder under reasonable terms and conditions and in a reasonable period of time, and Article 31(f) of TRIPS.

Obligations from the EU Association Agreement

The EU Association Agreement establishes a Deep and Comprehensive Free Trade Area and contains a number of requirements in the area of intellectual property protection that can have an impact on the affordability of medicines.

Article 279 requires Parties to the AA to provide for domestic or regional exhaustion of intellectual property rights. This provision limits the possibility of parallel importations of medical products to imports from countries within the European Union.

Article 314 requires the implemenation of supplementary protection certificates (see above).

Article 315 requires the protection of data submitted to obtain a market authorisation for a medicinal product. In addition, to guarantee the confidentiality, and non-disclosure of such data, the provision also requires that for five years (starting from the date of the grant of a marketing authorization in the Party
concerned) no one other than the person or entity who submitted data shall be allowed to rely directly or indirectly on it. For seven years a marketing authorization shall not be granted unless the applicant submits his/her own data, or gets a permission from the person or entity who submitted the data. This period can be extended to eight years if during the first five years the holder obtains an authorisation for new therapeutic indications of significant clinical benefit in comparison with existing therapies.

A law is currently tabled in Parliament (at the stage of second reading) that amends the Law No. 1456-XII of 25 May 1993 on Pharmaceutical Activity to introduce test data exclusivity in line with the requirements of the DCFTA. If adopted, the amendments would provide for data exclusivity for a period of up to eight years. The bill contains an exception for those pharmaceutical products that have been duly authorized anywhere in the world for at least eight years (Article 11, Paragraph 5). In the discussions, it was pointed out that if necessary, exceptions could still be introduced in this legislation during the parliamentary process.

Experience in Ukraine and with FTAs in other regions

Ukraine is one of the countries in the EECA region, where funding for ARV treatment is provided by both Global Fund grants and the state budget. The prices of second line ARVs (LPV/RTV) provided with GF grants are much higher than the GF Median Price, despite the relatively high volumes of procurement and the opportunities to achieve economies of scale. The same applies for some first line ARVs, in particular abacavir, the price of which is several times lower in most countries neighboring Ukraine, including Moldova. In Ukraine, during the period 2010-2013, the supply with the most frequently used dosage of abacavir (per patient per year) was more expensive than the supply with the most frequently used dosage of second line LPV/RTV. While there are several factors that explain the high ARV prices, TRIPS-plus provisions and their impact on the market contribute significantly to this process.

In 2008, as part of its WTO accession negotiations, Ukraine agreed on TRIPS-plus provisions that included test data exclusivity and patent registration linkage. The test data exclusivity regime was extended further during the FTA negotiations with EFTA (2010). A lacuna in the national law allowed a retroactive application and, as a result, two generic equivalents of LPV/RTV were taken off the market. In addition, the registration of a generic FDC was prevented and protracted litigation around generic efavirenz ensued. Intellectual property litigation arose around abacavir because an existing

patent on abacavir sulphate resulted in delays at customs of generic abacavir, which consequently drove prices very high.

Ukraine has since introduced some reforms into its regulatory framework. The country has completed the integration of a fast track regime for compulsory licensing at administrative level but has not used it. After the law reforms and the adoption of the regulations on compulsory licensing, prices of ARVs in Ukraine have decreased, even though they still remain relatively high.

Following this presentation, the typical cases of TRIPS-plus provisions introduced during the FTA negotiations were presented. It was stressed that usually these provisions target the expansion of the scope of protection and the creation of "monopolies" on the markets. Typical avenues for achieving this are the definition of patentability standards that allow the patentability of variations of existing chemical compounds and second medical use, patent-registration linkage, test data exclusivity, patent term extensions, restrictions of parallel importation through national exhaustion, and prohibition of pre-grant patent oppositions.

Analysis of the impact of TRIPS-plus provisions contained in a number of free trade agreements on public health systems in the Dominican Republic, Costa Rica, Colombia, Peru, Jordan and Thailand were mentioned.[7] It was stressed that countries that have signed TRIPS-plus commitments should still exert more effort to mitigate the negative impact of these commitments on access to treatment by using and utilizing the remaining public health-related flexibilities. As an example, Chilean authorities addressed the test data exclusivity requirements in a way that would limit its impact and safeguard compulsory licensing. According to Chilean law, data exclusivity will not be granted when the product has not been commercialized in Chile within 12 months from the date of registry or sanitary approval in the country; or the product has been authorized in a foreign country for more than 12 months. [Source: Decree 153 (2005) of the Chilean Health Ministry].
Similar examples were provided with the US-Australia FTA and the measures taken by Australia to limit patent term extensions and the "evergreening" of pharmaceutical patents.

Possible models of enhanced national cooperation

Two examples were presented on how other countries have enhanced national collaboration among the relevant Ministries, agencies and stakeholders with respect to public health and intellectual property policies. In Switzerland, an interministerial group was created that is co-chaired by the Swiss Federal Agency of Public Health and the Swiss Federal Office of Intellectual Property. All relevant Ministries are members of the group, including Swissmedic, State Secretariat of Economic Affairs, Swiss Agency for Development & Cooperation as well as Foreign Affairs to build trust among the different Ministries and to ensure policy coherence. Neither industry nor civil society is part of this group. This initiative has led to an increased understanding of the issue in the different Ministries and improved decision-making in the area with better outcomes for public health.

In Ukraine, a multi-stakeholder group on intellectual property and access to medicines was created under the Ministry of Health in 2010, which included representatives of the Medicines' Agency, the Ministry of Health, the Ministry of Foreign Affairs, the Ministry of Economy, the national intellectual property authorities, the Intellectual Property Institute at the Academy of Legal Sciences, civil society, and, in a consultative role, intergovernmental agencies such as UNDP, WHO and UNAIDS. Representatives of the originator industry were also present through a lobbyist organization, but there were no representatives of the local and international generic industry. As a result, the

[7] See for more details and references page 190 of: Promoting Access to Medical Technologies and Innovation. Intersections between public health, intellectual property and trade, WHO, WIPO, WTO 2012: http://www.who.int/phi/promoting_access_medical_innovation/en/

discussions around the regulations on compulsory licensing of medicines were protracted until late 2013, when the Government Regulations were finally adopted.

The discussion focused on the possible membership of such a group and the relevant experience in Moldova. Participants pointed out that participation of industry can be problematic if the group is meant to take decisions. If not part of such a group, stakeholders can be consulted separately.

Conclusions

General conclusions on the opportunities to use the public health related flexibilities in the TRIPS Agreement

1) The TRIPS Agreement has minimum obligations for WTO Member States, but also contains important flexibilities and exceptions that Member States should consider.
2) The Doha Declaration on the TRIPS Agreement and Public Health (2001) has clarified the policy space available to countries.
3) There are opportunities to mitigate TRIPS-plus commitments in order to reduce the potentially harmful impact on treatment access without infringing international obligations.
4) Countries should be mindful when signing free trade agreements or passing domestic legislation that impedes access to treatment.
5) The incorporation of flexibilities into domestic legislation should be guided by strategic domestic objectives and make sure that they are easy to use.
6) The implementation of TRIPS flexibilities can sometimes strengthen the position of the government in price negotiations (e.g. the case of Brazil and LPV/RTV).
7) Using the TRIPS Agreement public health flexibilities can help keeping national treatment programmes affordable in times of austerity.

Conclusions specific to the situation of access to medicines and intellectual property in the Republic of Moldova

Access to essential medicines in Moldova is still a challenge. There are many reasons for the current lack of access, including prices. Prices of medical products are influenced by different factors such as wholesaler and pharmacy mark ups. Different measures can be taken to improve access to essential medicines. These are outlined in detail in the WHO Report on Availability and Affordability of Medicines and Assessment of Quality Systems for Prescription of Medicines in the Republic of Moldova.[8]

The country's public health system relies heavily on generic equivalents, not only for HIV medicines but in general as well. Currently Moldova is procuring few patented products and the market share of patented products is very small. High prices, for example for cancer treatments, can be one

[8] See: http://www.euro.who.int/en/health-topics/Health-systems/medicines/publications2/2012/availability-and-affordability-of-medicines-and-assessment-of-quality-systems-for-prescription-of-medicines-in-the-republic-of-moldova

reason for the small market share of patented products in Moldova. In the area of HIV, only two products are sourced from originator companies.[9]

Moldova is bound by the WTO agreements and, since it has already been ratified, will also have to implement the additional requirements contained in the DCFTA with the EU - as per the alignment schedule to be set by the Association Committee in Trade configuration, Art 438(4) of the AA. The remaining policy space for amendments that could facilitate access to affordable medicines is therefore limited. The validation agreement between the AGEPI and the European Patent Office if ratified will further limit this policy space and will very likely lead to an increasing number of patents in Moldova, including in the pharmaceutical sector which would limit the opportunities to procure generic equivalents. When discussing ratification, the Parliament should consider this likely impact of the validation agreement.

National authorities may want to consider the introduction of a number of features in the respective laws or guidelines:

1) Include an exemption of "diagnostic, therapeutic and surgical methods for the treatment of humans or animals" from patentability in Articles 6 or 7 of the Law on Protection of Innovations.

2) Change the Regulations on the Procedure of Filing and Examination of a Patent Application and of Grant of a Patent to limit the patentability of first and second medical uses and provide for a strict definition and application of patentability criteria in the area of pharmaceuticals.

3) Include a Bolar-type exception in Article 22 of the Law that states that rights conferred by a patent shall not extend to activities that are undertaken to fulfill the requirements to get a market authorization for a pharmaceutical product in Moldova.

4) Include a sentence in the draft Article 11 of the Law No. 1456-XII of 25 May 1993 on Pharmaceutical Activity to allow the Ministry of Health to exempt essential medicines from data exclusivity if there is a public health need through an administrative procedure. In draft Article 11(5) of this law, change the exception for pharmaceutical products that have been authorized anywhere else in the world for at least eight years to one year. This measure would be an incentive for international companies to register any new pharmaceutical products early in Moldova.

5) Revise Article 28 of the Law on Protection of Innovations on compulsory licenses to allow the Ministry of Health to declare government use of essential medicines through an administrative procedure if there is a public health need, including unaffordable prices and to implement the WTO 30 August 2003 Decision on compulsory licenses for export/import to countries with limited manufacturing capacity. Adopt easy to use, expeditious compulsory licensing provisions in line with the WTO TRIPS Agreement ensuring that:

a) due process is followed and courts and litigation do not delay the effective deployment of compulsory licenses;
b) definite timelines are provided within which negotiations to obtain a voluntary license on reasonable grounds should take place; and

[9] Moldova is included in all the voluntary license agreements signed by the Medicines Patent Pool so far which allows the generic manufacturers that signed license agreements with the Pool to sell their products in Moldova.

c) the inclusion of more grounds under which a compulsory license can be issued (including anti-competitive behavior).

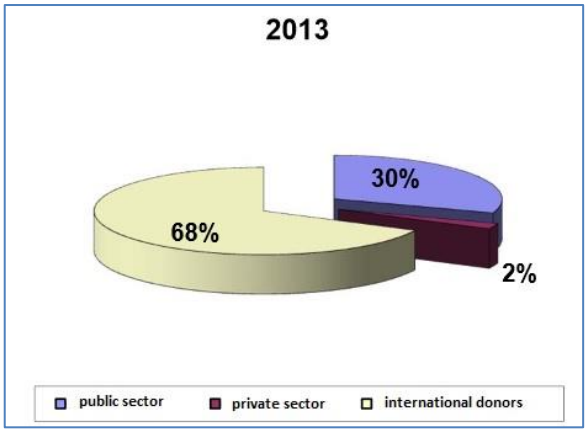
6) Introduce Guidelines that regulate remuneration (royalty) in case of compulsory licensing.[10]

7) Consider incorporating, where appropriate in intellectual property legislation, a provision on remedies for anti-competitive behavior in line with Articles 31 (k) and Article 40 of the TRIPS Agreement.

Background

While globally the number of new HIV infections is decreasing, EECA is home of a still further growing HIV epidemic, rising from an estimated 970,000 people living with HIV in 2001 to almost 1.6 million in 2013. Mortality from AIDS has also increased by 21% in the region over the period 2005-2011. The Russian Federation and Ukraine, the two most populous EECA countries, together account for almost 90 percent of newly reported HIV cases.

Access to ARV treatment in the region remains a significant challenge. Despite improvements over the past decade, if the 2010 WHO recommendations for starting treatment are applied, it is still low with only about 35 percent of the adults in need receiving treatment. Some estimates have indicated that per the recommendations of the 2013 Consolidated WHO guidelines on HIV prevention, diagnosis, and treatment,[11] the percentage of persons in need who receive treatment in the region could be much lower.



Over time, due to development of treatment resistence, more and more people on treatment would have to use second line medicines, which are significantly more expensive. High costs of fixed dose combinations and some pediatrics also cause serious concern. At the same time, costs of certain anti-retroviral medicines, especially second-line (but also some first line medicines), remain very high compared to the Global Fund Median Price and prices from other regions, according to the Global Fund Price and Quality Reporting Mechanism and the WHO GPRM. The increased need in treatment requires attention also because of the new mechanism of financing national HIV responses. The New Funding Model of the Global Fund calls for increased national co-financing of the responses and reduces the eligibility of countries for funding.[12] Recently, the Global Fund Observer, an independent publication of Aidspan, made a comparison between current levels of GF funding and allocations, according to which EECA as a region will experience a net decrease in GF allocations.[13]

[10] WHO, UNDP, Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies, 2005, www.who.int/hiv/amds/WHOTCM2005.1_OMS.pdf

[11] Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection, WHO 2013, http://www.who.int/hiv/pub/guidelines/arv2013/en/

[12] The Global Fund, New Funding Model, http://www.theglobalfund.org/en/fundingmodel/

[13] David Garmaise, Funding for lowest income countries up by more than 20% under new funding model allocations, 2014, the Global Fund Observer, http://www.aidspan.org/gfo_article/funding-lowest-income-countries-more-20-under-new-funding-model-allocations

Given its proximity to the European Union and the accession of a number of countries of the region to the WTO, the level of protection of intellectual property rights in the region is gradually increasing. Patent protection and data exclusivity as a form of protection of pre-clinical and clinical test data submitted to national regulatory agencies can delay the entry of generic products into the market and consequently have a negative impact on prices. Accession agreements to the WTO as well as bilateral or regional (trade) agreements can also limit the ability of countries to use the flexibilities in the WTO TRIPS Agreement that can be used to facilitate access medicines. It was reemphasized in the WTO Ministerial Declaration on the TRIPS agreement and public health (Doha Declaration) that countries can and should be able to use these flexiblities.[14] To assess the impact of individual agreements and the flexibilities that remain requires a thorough case-by-case analysis. It is essential that when these agreements are implemented in national legislation, health aspects are taken into account and are implemented in a way that promotes generic competition.

In this context, Ukraine has been a frequently discussed case, with the registration of two generic ARVs and the prevention of the registration of an FDC, after its WTO accession in 2008 and the adoption of "test data exclusivity".

According to the 2014 Country Progress Report,[15] the Republic of Moldova is classified as a country with low HIV prevalence and an HIV epidemic concentrated among people who inject drugs. There is, however, evidence of spread of the infection in the general population. Almost 70% of the funding in HIV in the country comes from international donors. The relative share of expenditure for treatment has almost doubled over the past two years. In 2013, it was 40% of the total spending, compared to 33% in 2012 and 25% in 2011.[16]

The Republic of Moldova has been a Member of WTO since 26 July 2001 and is therefore bound to implement the WTO TRIPS Agreement. On 27 June 2014, Moldova signed the AA with the EU, which includes a Deep and Comprehensive Free Trade Agreement (DCFTA). The AA was ratified by the Moldovan Parliament on 2 July 2014 and the European Parliament in November 2014. The agreement once entered into force will require Moldova to introduce certain amendments in its domestic legislation and this process has already started, including in the field of intellectual property. Intellectual property matters are regulated by Chapter 9 of the Agreement, and by various other sections and annexes to the document.

[14] The Declaration adopted in 2001 says that "the TRIPS Agreement does not and should not prevent members from taking measures to protect public health" and reaffirms "the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose" meaning the promotion of access to medicines for all (http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm). This Agreement was reiterated in the Global Strategy and plan of action on public health, innovation and intellectual property adopted by the World Health Assembly in 2008 that encourages countries to implement and where necessary use TRIPS flexibilities to improve access to medicines.

[15] UNAIDS, Republic of Moldova, Progress Report HIV, January 2012 – December 2013, Chisinau 2014.

[16] As per data of the 2014 Country Progress Report.

Reference Materials

- WHO, Policy Paper on Affordianbility and Availablity of Medicines in Moldova http://www.euro.who.int/en/countries/republic-of-moldova/publications2/health-policy-paper-series-no.6-availability-and-affordability-of-medicines-and-assessment-of-quality-systems-for-prescription-of-medicines-in-the-republic-of-moldova
- UNAIDS, UNDP and WHO Joint Policy Brief on TRIPS and Access to Medicines http://www.undp.org/content/dam/aplaws/press_release/en/2011/march/unaids-undp-who-concerned-over-sustainability-of-hiv-treatment/PolicyBrief-TRIPS_eng.pdf
- WHO, WIPO, WTO, Promoting Access to Medical Technologies and Innovation. Intersections between public health, intellectual property and trade, 2012 http://www.who.int/phi/promoting_access_medical_innovation/en/
- WHO, Increasing access to HIV treatment in middle-income countries: Key data on prices, regulatory status, tariffs and the intellectual property situation, 2013 http://www.who.int/phi/publications/hiv_increase_access/en/
- UNAIDS and UNDP Issue Brief on FTAs and access to treatment http://www.undp.org/content/dam/undp/library/hivaids/Issue%20brief%20-%20Potential%20impact%20of%20free%20trade%20agreements%20on%20public%20health.pdf
- UNDP Good Practice Guide on Utilizing the TRIPS Agreement Public Health Flexibilities http://www.undp.org/content/dam/aplaws/publication/en/publications/poverty-reduction/poverty-website/good-practice-guide-improving-access-to-treatment-by-utilizing-public-health-flexibilities-in-the-wto-trips-agreement/Good%20Practice%20Guide-Improving%20access%20to%20treatment%20by%20utilizing%20public%20health%20flexibilities%20in%20the%20WTO%20TRIPS%20agreement.pdf
- UNDP, Study on Using Competition Laws to Promote Access to Medicines http://www.undp.org/content/dam/undp/library/HIV-AIDS/Governance%20of%20HIV%20Responses/UNDP-Using%20Competition%20Law%20to%20Promote%20Access%20to%20Medicine-05-14-2014.pdf

Annex I: Agenda

National Consultations on
Access to HIV Treatment and Other Essential Medicines and Intellectual Property

18-19 November 2014
Hotel Codru, the Courtyard Room
127, 31 August 1989 Str., Chisinau, Republic of Moldova

Time	Day One, 18 November, Tuesday
9:00 - 9:20	Opening and Introduction of Participants
9:20 – 10:00	Access to HIV Treatment and other essential medicines in the Republic of Moldova. The role of IP and the ongoing legislation reform. Positions of the government and civil society (brief narrative inputs from representatives of Ministry of Health, AGEPI, other authorities, civil society)
10:00 – 11:00	The Impact of IP on Access to and Cost of Medicines – an introduction Tenu Avafia (UNDP): History of IP development: a brief overview. The position and work of UNDP on IP and Access to ARVs Peter Beyer (WHO): Intellectual property rights and access to medicines: a general introduction
11:00 – 11:15	Questions and Answers (Q&A)
11:15 – 11:25	Break
11:25 – 12:00	The situation with cost of and access to ARV medicines in Moldova. The GF NFM, UNAIDS investment case, and need to secure sustainable financing of national HIV responses. Overview by Silviu Ciobanu (WHO). Input by Svetlana Plamadeala (UNAIDS), the Ministry of Health and the Medicines' Agency, civil society
12:00 – 12:10	Q&A
12:10 – 13:00	The TRIPS Agreement Public Health Flexibilities and their importance for access to essential medicines, including HIV treatment. Presentation by Peter Beyer and Tenu Avafia
13:00 – 14:00	Lunch
14:00 – 14:15	The experience of Ukraine in access to medicines – lessons learned and recommendations. Presentation by Boyan Konstantinov, input from all participants
14:15 – 15:00	IP Commitments of Moldova in the context of WTO accession and the ratified AADCFTA: comparison with current national legislation. National Experts of the Republic of Moldova (AGEPI and other institutions). Input from Tenu Avafia, Peter Beyer, Boyan Konstantinov, other authorities, civil society
15:00 – 15:10	Discussion
15:10 – 15:20	Break
15:20 – 16:00	The "TRIPS-minus", "TRIPS" and "TRIPS- plus" standards of IP protection and enforcement. The role of free trade agreements in introducing these standards. The likely impact on the public health systems. Lessons learned from some Arab states and countries in America region. Mohammed El Said, UCLAN (via Skype)
16:00 – 16:15	Q&A
16:15 – 17:15	Opportunities to maximize policy space and to mitigate likely negative consequences of TRIPS-plus standards on access to medicines. Global examples and opportunities for application in the context of Moldova. Input from all participants, questions and answers, discussion.
17:15 -17:30	Wrap up and closure of Day One

	Day Two, 19 November, Wednesday
9:30 – 10:30	Summary of Day One – presentation of the problematic topics outlined (UNDP and WHO) and the discussions

10:30 – 11:00	Availability and affordability of medicines and assessment of quality systems for prescription of medicines in the Republic of Moldova. Andrei Matei (WHO)
11:00 – 11:15	Break
11:15 – 12:30	Break Next Steps: mapping of stakeholders involved in the process of IP commitments' transposition and legislation harmonization. Discussing the opportunities to integrate public health priorities in the process and avenues to achieve this. Outlining the possible engagements of government authorities, civil society, UN agencies, and EU partners in this process.
12:30	Closure and Lunch

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