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Tuberculosis control and human rights in the national legislation of Ukraine

Report of a mission 20–24 April 2015

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ABSTRACT

In October 2013, the WHO Regional Office for Europe organized a regional workshop on tuberculosis, ethics and human rights. As part of the follow-up, a mission was conducted to Ukraine on 20–24 April 2015 with the following objectives: (i) to assess national primary and secondary legislation governing the involuntary isolation and treatment for TB and the compassionate use of new anti-TB drugs; (ii) to initiate a policy dialogue with the major national and international stakeholders in the country; and (iii) to develop specific recommendations for the alignment of existing legislation with the international treaties, conventions and declarations adopted by Ukraine and with WHO's recommendations on ethics and human rights. Specific recommendations from the mission included the need to: (i) update current legislation and operational guidelines to limit involuntary isolation, and (ii) make use of the existing legislative framework for importing much needed new anti-TB drugs such as delamanid and bedaquiline.

Keywords

HUMAN RIGHTS – legislation and jurisprudence
TUBERCULOSIS, MULTIDRUG-RESISTANT – prevention and control
EXTENSIVELY DRUG-RESISTANT TUBERCULOSIS – prevention and control
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Abbreviations

| | |
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| CPC | Civil Procedural Code |
| ECHR | European Convention on Human Rights |
| ECtHR | European Court of Human Rights |
| ICCPR | International Covenant on Civil and Political Rights |
| M/XDR-TB | multidrug and extensively drug-resistant TB |
| TB | tuberculosis |
| UNCESCR | UN Committee on Economic, Social and Cultural Rights |

Introduction

In October 2013, the WHO Regional Office for Europe organized a regional workshop in Copenhagen on tuberculosis (TB), ethics and human rights (1). As part of the follow-up to that workshop, a mission was conducted to Ukraine on 20–24 April 2015 by Professor Stéphanie Dagon of the Swiss National Science Foundation and the University of Geneva, Switzerland, with the main purpose of assisting the national TB programme in promoting human rights and practices based on sound ethical standards in the management of M/XDR-TB. This report covers the findings of that mission.

The mission focused on Ukrainian legislation authorizing the involuntary isolation or hospitalization of TB patients, and defined the conditions for access to drugs for multidrug and extensively drug-resistant TB (M/XDR-TB) patients in Ukraine. The objectives of the mission were:

- to assess the national primary and secondary legislation governing the involuntary isolation and treatment for TB and the compassionate use of new anti-TB drugs;
- to initiate a policy dialogue with the major national and international stakeholders in the country;
- to develop specific recommendations for the alignment of existing legislation with international treaties, conventions and declarations adopted by Ukraine and with WHO's recommendations on ethics and human rights.

The assessment was guided by the international and European human rights standards guaranteed by the treaties ratified by Ukraine. Some of these standards are reiterated in WHO's *Guidance on the ethics of tuberculosis prevention, care and control* (2).

Interviews were conducted with representatives of the main political players (Ministry of Health, Legal Department), Ministry of Justice (Department of Constitutional, Administrative and Social Law), Ministry of Social Policy of Ukraine and the Secretariat of the Parliamentary Committee on Health), the main public actors in the field of TB and drug control and management (national TB programme, Regulatory Authority on Pharmaceuticals, State Service on Pharmaceutical Products), representatives of the Office of the Parliamentary Commissioner for Human Rights, nongovernmental organizations involved with TB patients (National Red Cross Society, All-Ukrainian Board on Patients' Rights and Security Protection, AIDS Alliance, Network of People Living with HIV/AIDS) and representatives of international organizations in Kyiv involved in the fields of health and/or human rights (WHO, United Nations Human Rights Monitoring Mission in Ukraine attached to the Office of the United Nations Commissioner for Human Rights) (Annex 1).

Country context

Discussions focused on progress in the field of TB control and management as well as the existing national TB programme.

The level of MDR-TB is one of the highest in the world. This situation is aggravated by the more general problems mentioned by all stakeholders interviewed, including the pressing needs to: (i) develop outpatient treatment; (ii) increase the capacity of primary health care physicians to

diagnose TB effectively; (iii) improve the electronic register to allow a better appraisal of actual needs in services and medicines; and (iv) find suitable and sustainable solutions in the field of drug procurement.

It has been often asserted that the protection of the human rights of patients, specifically the rights of TB patients, is at the centre of current developments in legislation in Ukraine. These concerns dictated the changes introduced in Law No. 2585-III of 5 July 2001 On Countering TB¹ that were presented as progressive and respectful of human rights standards. Specifically, the 2012 revision introduced procedural rules for the use of involuntary hospitalization² as a new measure to control the spread of TB. Even though trends show a reduction in forced hospitalization, all stakeholders recognized that the situation is not satisfactory. There are gaps in the normative instruments and the practices developed for their implementation and they do not necessarily accord with human rights standards (see below).

Discussions with the stakeholders during the mission focused on improving the social determinants of health. Such determinants are essential to the attainment of TB control targets and are specifically relevant in the context of the use of involuntary isolation. They include access to food and proper housing and environmental conditions as well as financially, geographically and culturally acceptable access to health care. Their presence strongly influences the distribution of TB within the population, particularly adherence to and success of treatment (4). Social determinants of health are, therefore, strongly related to the development of non-coercive measures that should be taken before involuntary isolation is resorted to. These measures, which aim to support the patient during treatment, can take the form of food vouchers, financial allowances or support in finding proper accommodation. However, the approach of the National Targeted Social Programme to Fight TB in 2012–2016, adopted in the form of a statute,³ does not consider the social determinants of health. The support provided by the public authorities in the field of social policy seems to be restricted to the provision of information to the family members of TB patients and to financial and social support in cases of invalidity. Although the allocation of invalidity pensions is well organized and accessible to the patients concerned, such pensions are not relevant to a large majority of TB patients.

The National Targeted Social Programme to Fight TB 2012–2016 focuses solely on the need to improve the involvement of civil society organizations in the fight against TB. In fact, these organizations have developed activities related to the social determinants of health. They are generally involved in work with vulnerable groups and persons confronted with HIV/TB coinfections and give support to patients who are no longer infectious and who continue their treatment in an outpatient setting. Nongovernmental organizations generally provide assistance for the application of directly observed treatment in outpatient settings. These programmes are not, however, funded by the government but are totally dependent on international funding and the free will of the benevolent (at least in the case of the Ukrainian Red Cross Society). Neither can they be pursued on a systematic basis. The results are very encouraging when the organizations/programmes can intervene but they do not have the capacity to offer every patient

¹ Law of Ukraine No. 2586-III of 5 July 2001 On Countering TB (hereafter the law on countering TB), as amended by the Law of Ukraine No. 4565-VI of 22 March 2012 On Amendments to The law of Ukraine ‘On Countering TB’ and other legislative acts of Ukraine. On this law, see the analysis below. All laws, orders and resolutions are available on the website of the Verkhovna Rada of Ukraine (3).

² Involuntary hospitalization has the same meaning as involuntary isolation or detention. The human rights law more commonly uses isolation or detention.

³ Law of Ukraine No. 5451-IV of 16 October 2012 On Adopting the National Targeted Social Programme for Countering Tuberculosis in 2012–2016.

regular psychological support, food packages, financial support for transport, work counselling (efforts regarding coordination with the public work centres were mentioned) or support with housing.

Discussions were also conducted with the stakeholders regarding access to TB drugs in general and, in particular, access to drugs under development for compassionate use for M/XDR-TB patients. The public authorities and other stakeholders (such as nongovernmental organizations or WHO) are concerned at the moment with the central question of access for all to the first- and second-line TB drugs on a regular basis and at an affordable price. Efforts and financial resources should be invested in improving the quality of health care and access to these TB drugs and developing social support before the question of access to drugs under development is discussed. Laws No. 269-VIII On Amendments to Certain Regulations of Ukraine Regarding Provision of Timely Access of Patients to Essential Pharmaceuticals and Medical Products through Public Procurement, Assisted by Specialized Procurement Organizations (19 March 2015) and No. 332-VIII On Amendment to the Tax Code of Ukraine Regarding Exemption from Taxation of some Medications and Medical Products (9 April 2015) had been adopted to help reduce the costs of drugs and to avoid the difficulties inherent in the system of public procurement. Although these laws should enable drug procurement to be transferred to United Nations agencies, such as the United Nations Children's Fund and WHO, there seem to be extreme difficulties in the transfer process to these international agencies. These difficulties are at the centre of efforts by the stakeholders, who consider the question of access to drugs under development for M/XDR-TB patients as secondary. Discussions had been conducted regarding the changes to be introduced soon in the legislative framework aiming to facilitate rapid access to new drugs that are not registered in Ukraine but have received at least marketing approval in another country.

The protection of human rights relevant in the context of TB

Human rights related to health guaranteed under Ukrainian law

The Ukrainian Constitution adopted in 1996⁴ guarantees a general commitment to human rights and freedoms (art. 3). It also provides that “a man, his life and health, honour and dignity, inviolability and security, shall be recognized” as having “the greatest social value”. Title II of the Constitution (art(s). 21–68) contains a long list of provisions regarding fundamental rights, starting with a reaffirmation in art. 21 of the centrality of the principles of equality and non-discrimination as well as the inalienability and inviolability of human rights. Several human rights and freedoms are particularly relevant in the context of TB. These include equality before the law (art. 24.1), the right to life (art. 27.1), the right to be free from “torture, cruel, inhumane, or degrading treatment or punishment that violates his dignity” (art. 28.2), the right to freedom and personal inviolability (art. 29), and freedom from interference in “private life and family matters” (art. 32). Art. 46 guarantees the “right to social protection including the right to financial security” in cases of, inter alia, disability and old age (art. 46.1) and establishes a “mandatory state social insurance” (art. 46.2).

The right to health is not explicitly guaranteed. The Constitution does, however, guarantee many components of the right to health: art. 24 (on equality before the law) contains a reference to the

⁴ The Constitution of Ukraine was adopted, ratified and entered into force at the 5th session of the Parliament on 28 June 1996, replacing the former Constitution (Fundamental Law). The text of the Constitution is available in English (3).

protection of the health of women; art. 27 (on the right to life) guarantees the right of everyone “to protect his life and health, and lives and health of other people against unlawful encroachments”; art. 43 (on the right to work) stipulates the “right to proper, safe, and healthy labour conditions”; art. 48 guarantees the right of everyone to a “standard of living sufficient for themselves and their families including adequate nutrition, clothing, and housing” and, finally, art. 50 guarantees the right of everyone “to an environment that is safe for life and health, and to compensation for damages caused by violation of this right.” Art. 49 enshrines the right of everyone to “health protection, medical care and medical insurance” and specifies that health protection is funded by the Ukrainian state. The latter is responsible for ensuring the accessibility of effective medical services. Furthermore, pursuant to art. 49, all state- and community-owned “health protection institutions ... render medical care free of charge” whereas the state is at the same time held to promote the “development of medical institutions under all forms of ownership”. The network of state- and community-owned health protection institutions “shall not be reduced”. Finally, art. 49 also establishes the state’s responsibility for promoting “physical culture and sports” and, more importantly, its responsibility to ensure “sanitary-epidemic welfare”.

These constituent elements of the right to health were included in Law No. 2801-XII of 19 November 1992 On the Fundamentals of Health Care (hereafter law on the fundamentals of health care). Art. 6 of this law contains a long list of services and goods related to the right of every citizen to health care. This list includes protection of the social determinants of health (food, shelter), access to quality health care services, participation in the definition of health policies and in the management of these policies, protection against discrimination in the field of health care and, more basically, protection of human rights in this area.

The protection of human rights in Ukraine is reinforced through the application of international human rights law. According to art. 22 of the Constitution, the list of human rights guaranteed by the Constitution is not exhaustive. Ukraine has ratified the most important international and European human rights treaties (Table 1). The rights to protection of health, to social security and to medical assistance are also included in the revised European Social Charter, ratified by Ukraine on 21 December 2006. National judicial and nonjudicial mechanisms exist, as do European (European Convention on Human Rights and the European Committee of Social Rights) and international (human rights treaty-based bodies) judicial and nonjudicial mechanisms for the protection of human rights. The Constitutional Court is the sole body which has jurisdiction over constitutional issues in Ukraine. The national institution for human rights is the Parliamentary Commissioner for Human Rights (also referred to as the Ombudsman), created by Law No. 776/97-BP On the Ukrainian Parliament Commissioner for Human Rights of 23 December 1997 (5). Art. 55 recognizes the competence of “relevant international judicial institutions” and “relevant bodies of international organizations of which Ukraine is a member or participant” for individual appeals after exhaustion of domestic legal recourse.

Special human rights topics in the field of health and TB

Emerging human rights challenges in the eastern regions of Ukraine

Ukraine is facing a difficult political and economic situation with a high number of internally displaced people and refugees. As far as the right to health is concerned, including access to medical services, these people qualify as a particularly vulnerable group. Furthermore, there are disruptions in the payment of salaries, pensions and social benefits for those living in non-government-controlled areas. Great difficulties have been reported in following up TB patients among those internally displaced and refugees in the new places where they are temporarily living.

Table 1. Treaties, conventions and declarations relevant to TB and human rights protection signed or ratified by Ukraine

| International treaty | Signature | Ratification |
|---|-------------------|-------------------|
| International Covenant on Civil and Political Rights (ICCPR) (16 December 1966) | 20 March 1968 | 12 November 1973 |
| First Optional Protocol to the ICCPR (16 December 1966) | | 25 July 1991 |
| International Covenant on Economic, Social and Cultural Rights (16 December 1966) | 20 March 1968 | 12 November 1973 |
| Optional Protocol to the International Covenant on Economic, Social and Cultural Rights (10 December 2008) | 24 September 2009 | Not yet ratified |
| International Convention on the Elimination of All Forms of Racial Discrimination (7 March 1966) | 7 March 1966 | 7 March 1969 |
| Convention on the Prevention and Punishment of the Crime of Genocide (12 January 1951) | 16 December 1949 | 15 November 1954 |
| Convention on the Rights of the Child (20 November 1989) | 21 February 1990 | 28 August 1991 |
| Convention on the Elimination of All Forms of Discrimination against Women (18 December 1979) | 17 July 1980 | 12 March 1981 |
| Convention on the Rights of Persons with Disabilities (13 December 2006) | 24 September 2008 | 4 February 2010 |
| European Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR, 4 November 1950) ^a | 9 November 1995 | 11 September 1997 |
| European Convention for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment (26 November 1987) ^a | 2 May 1996 | 5 May 1997 |
| Revised European Social Charter (3 May 1996) ^a | 7 May 1999 | 21 December 2006 |
| Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (4 April 1997) ^a | 22 March 2002 | Not yet ratified |

^a In the context of the European Council.

Protection of economic and social human rights

Ukraine has faced considerable difficulties with the realization of economic and social human rights. The report of the Office of the United Nations Commissioner for Human Rights on the situation of human rights in Ukraine dated 15 April 2014 (6) identified two major underlying human rights violations: corruption and violations of economic and social rights, as well as the lack of accountability for human rights violations and institutions for the rule of law. According to the report, “corruption has disproportionately affected the poor and the most vulnerable” and thereby negatively impacted “on the enjoyment by all of economic and social rights, including the right to health services” (6).

The report further states that:

... [h]ealth service allocations make up 3.5% of the country’s GDP, which falls well short of the minimum recommended by the WHO (7%). The poorest segment of the population cannot afford costly treatment in a situation where the country has no medical insurance system. The Ministry of Health supports reform of management of medical services to move away from a centralized medical system and enable greater medical self-governance. Insufficient salaries for employees in the health service have led to emigration of qualified staff. It has also affected professional competency and fed corruption practices, thus leading to inequalities in access to health care.

According to the law on countering TB, patients receive medical care, tuberculin diagnostics, chemoprophylaxis, rehabilitation in a sanatorium and anti-TB drugs free of charge. Incidents of discrimination affecting the diagnosis and treatment of drug-sensitive as well as MDR-TB patients were, however, reported during the mission, as described below.

- Stigmatization is a real problem that particularly affects TB patients who are former detainees as well as patients with HIV coinfection or those suffering from alcohol or drug addictions.
- Homeless people suffering from TB are not always registered with the national TB register and encounter difficulties in receiving health care.
- Social protection for TB patients is inadequate. Allowances for patients unable to work have only been allocated to a small percentage. Most TB patients are unemployed or doing temporary work. Social support is heavily dependent on the local authorities and their willingness to offer specific packages for TB patients. It is rare that nongovernmental organizations have the capacity to distribute food packages or give allowances for transport on a regular basis.
- Social protection for people such as social workers, who give medical and social support to patients ill with TB, is not specifically regulated.⁵ Only medical doctors have specific protection.
- No proper health care service is offered to M/XDR-TB patients who refuse to be hospitalized. It was reported that involuntary hospitalization is not used when it is confirmed that there is no treatment available for specific resistant forms of TB. According to some of the interviewees, the situation is particularly difficult for M/XDR-TB patients, with too few palliative care beds. Nongovernmental organizations are neither used to support infectious M/XDR-TB patients nor involved in the delivery of DOTS for noncontagious patients continuing their treatment on an ambulatory basis.
- Social support is largely dependent on local authorities and their willingness to offer specific support to TB patients. This system leads to discrimination between patients according to their place of residence.

International and European human rights standards in the fields of involuntary isolation, forced treatment and access to drugs under development for compassionate use

Ukraine is bound by its international commitments. The protection of these guaranteed human rights imposes three types of obligation on the state: to respect, protect and fulfil them. The last obligation is highly relevant in the context of this report. It requires the state to adopt appropriate legislative measures necessary to fulfil these rights. In the field of TB control, and in accordance with the questions dealt with in this report, the standards to be respected are as follows.

Forced treatment

According to international human rights law, medical treatment should not be administered without consent. This principle is guaranteed by the right to self-determination and autonomy

⁵ On the other hand, social protection regarding HIV/AIDS is explicitly regulated by Law No. 155/9-BP of 3 March 1998 On amendments to the law of Ukraine 'On prevention of AIDS and social protection of the population of 3 March 1998', which articulates "... prevention of AIDS and social protection of the population" for medical personnel and other persons, whose profession involves the risk of HIV infection (Chapter V).

(ICCPR, art. 1), the right not to be subjected to torture or to inhuman or degrading treatment (ICCPR, art. 7; ECHR, art. 3), the right to the security of the person (ICCPR, art. 9), the right to physical integrity (ICCPR, art. 17; ECHR, art. 8), and the right to health (International Covenant on Economic, Social and Cultural Rights, art. 12).

The United Nations Committee on Economic Social and Cultural Rights (UNCESCR) interprets the right to health by including freedoms and entitlements. It defines freedom as having “the right to control one’s health and body ... and the right to be free from interference, such as the right to be free from ... non-consensual treatment ...” (7).

However, this principle is not absolute. There are two exceptions that are recognized, namely for the treatment of mental illness or the prevention and control of communicable diseases (7). The UNCESCR reiterated that forced treatment is acceptable on an exceptional basis. The European Court of Human Rights (ECtHR) confirmed this interpretation as seen in the case of *Acmanne and others v. Belgium* [1984] (8). Interference with an individual’s freedom of choice within the sphere of health care must be prescribed by law and can only be justified if it is proportionate and “necessary in a democratic society”.

So far, the ECtHR has never rendered a decision concerning the forced administration of TB treatment. But a parallel analysis can be drawn from the case law of the Court concerning the force-feeding of prisoners in order to affirm that forced treatment in the case of TB would constitute a violation of the ECHR. In one case, the Court has decided that the methods used to force-feed a detainee on hunger strike constituted torture prohibited by art. 3 of the ECHR (9). It has also ruled that the non-imposition of a force-feeding measure in the case of a prisoner who refused to eat and who died as a result of a hunger-strike did not constitute a violation of the ECHR (10). The ECtHR also ruled that passive euthanasia, which requires only the withholding of treatment, does not appear to violate the right to life guaranteed by art. 2 of the ECHR. The right to life guarantees that the life of an individual remains protected against the state and against encroachments by others. It does not impose a duty to live.

The interpretation asserting that administering a TB treatment without the consent of the patient is an intrusive major intervention that constitutes a prohibited interference with a person’s rights under the ECHR is reinforced by the *Guidance on ethics of TB prevention, care and control* (2) which considers it unethical to force TB patients to undergo treatment if they have objected to it. Forced treatment in the case of TB requires “a repeated invasion of bodily integrity” and, “as a practical matter, it would be impossible to provide effective treatment without the patient’s cooperation”.

Involuntary isolation/detention

Involuntary isolation is restricted by art. 9 of the ICCPR which guarantees everyone’s right to liberty and security. According to the conditions enumerated in art. 9, detention should not be arbitrary, otherwise it will constitute a violation. Detention must, in all circumstances, be reasonable and necessary, and the decision to keep a person in detention should be open to periodic review and should not continue beyond the period for which the state can provide proper justification. Detention should also be prescribed by law. In other words, the substantive grounds and procedural rules for detention must be prescribed by law and should be clearly and unambiguously defined.

These standards have been confirmed by the UNCESCR in the field of public health. It recalls that the fulfilment of the obligations for the protection of public health does not authorize the limitation of the exercise of other fundamental rights. The tension between these two dimensions, individual and collective, is obvious in cases where issues of public health are improperly used as grounds for restrictions. According to the UNCESCR:

... a State party which, for example, restricts the movement of, or incarcerates, persons with transmissible diseases such as HIV/AIDS, refuses to allow doctors to treat persons believed to be opposed to a government, or fails to provide immunization against the community's major infectious diseases, on grounds such as national security or the preservation of public order, has the burden of justifying such serious measures in relation to each of the elements identified in article 4. Such restrictions must be in accordance with the law, including international human rights standards, compatible with the nature of the rights protected by the Covenant, in the interest of legitimate aims pursued, and strictly necessary for the promotion of the general welfare in a democratic society. (...) [S]uch limitations must be proportional, i.e. the least restrictive alternative must be adopted where several types of limitations are available. Even where such limitations on grounds of protecting public health are basically permitted, they should be of limited duration and subject to review. (7, paras 28,29)

Similar standards are applied in the European context. Art. 5 of the ECHR authorizes the detention of persons to prevent the spread of infectious diseases. The detention should be decided in accordance with the substantive and procedural rules clearly defined by law and is only justified when necessary on the basis of the given circumstances. In the case of *Enhorn v. Sweden* [2005], the ECtHR considered that one of the essential criteria when assessing the lawfulness of the detention was to determine “whether detention of the person infected is the last resort in order to prevent the spreading of the disease, because less severe measures have been considered and found to be insufficient to safeguard the public interest” (11).

With regard to the principles enounced above, the legislator should bear in mind that the deprivation of liberty and forced treatment will not be legitimated just by having a legal basis, per se. It is important to insist on the fact that coercive measures are necessary to attain the overall purpose of protecting the population from TB and MDR-TB and to safeguard the rights of individuals affected by these measures. The application of coercive measures has to be justified and must not cause needless or unreasonable harm to those affected. The introduction of coercive measures should be substantiated by scientific evidence, taking into account the socioeconomic particularities and the culture of the country concerned.

Access to drugs under development for compassionate use

Compassionate use refers to interventions under which the administration of a drug in the final stages of development will be made possible for individuals or for a group of patients⁶ with a chronically or seriously debilitating or life-threatening disease who cannot be treated satisfactorily with an authorized product.⁷

So far, the right of access to experimental drugs under certain circumstances has not been expressly interpreted as guaranteed by human rights law.

⁶ See the terminology used in the 2014 *Companion handbook to the WHO guidelines for the programmatic management of drug-resistant tuberculosis* (12). Compassionate use as a “named patient” programme is also envisaged by Directive 2001/83 of the European Parliament (art. 5) (13).

⁷ This definition is used by the European Union. See art. 83 (2) of EC Regulation 726/2004 of 31 March 2004 (14).

In the case of *Hristozov and Others v. Bulgaria* [2012], the ECtHR refused to take a position on the possible right of patients with serious and life-threatening illnesses, for which no comparable or satisfactory alternative drug or treatment is available, to have access to drugs that have not yet been licensed.⁸ The Court refused to acknowledge that there is an obligation for states to frame their domestic legislation in such a way as to entitle certain patients to have access to a drug under development. According to the Court, states are free to decide how to regulate access to such drugs for terminally ill patients.

In this case, however, the ECtHR also noted that the positive obligations of states under art. 2 of the ECHR may include the duty to take into account cases where conventional forms of medicinal treatment appear insufficient. According to the Court, the fulfilment of these positive obligations can be illustrated by the Bulgarian legislation which authorizes, in a restricted number of cases, access to drugs not registered in Bulgaria but registered in other European countries.

This interpretation of state practice might evolve differently in the near future. National legislative solutions in the area of pharmaceuticals take into account the rapid evolution of technologies in the field of drug development that allows for a different appraisal of safety issues as well as the special needs of patients with rare or infectious diseases. A growing number of states authorize, under certain circumstances, access to drugs under development. Some national regulatory agencies (the Food and Drug Administration for the United States and the European Union (EU) European Medicines Agency) also have the possibility to use new procedures which allow rapid access to specific drugs at an early stage of development (so-called conditional marketing authorization). The acceptance of a different level of risk where the needs of individuals (in the case of rare diseases) or the needs of entire societies (in the case of infectious diseases such as ebola⁹) is at stake, has already changed.

Legislative framework on forced treatment and involuntary isolation in Ukraine

The following remarks should be noted.

- Forced treatment understood as forced administration of medical treatment is not used in Ukraine for the treatment of TB, neither is it foreseen by the law on fundamentals of health care (3). Moreover, art. 10 (2) of the latter necessarily requires the written informed consent of the patient to undergo TB treatment.
- The term “forced hospitalization” is not defined by the applicable legislation. It is, however, used synonymously with involuntary isolation. In practice, it constitutes an infringement of the right to liberty and security. The use of forced hospitalization should, therefore, respect the international and European standards applicable in cases of involuntary isolation, otherwise it would constitute a human rights violation.

⁸ *Hristozov and others v. Bulgaria*. In this case, the Court ruled that “Article 2 of the Convention cannot be interpreted as requiring access to unauthorised medicinal products for the terminally ill to be regulated in a particular way” (15).

⁹ See the report of an advisory panel to WHO on the ethical considerations for use of unregistered interventions for Ebola virus disease (16).

Applicable legislative framework

The law on countering TB of 5 July 2001, as revised, defines the legal, organizational and financial basis for public activities in the field of TB. The objectives of the law are basically the prevention of TB and of the spreading of the disease as well as the provision of health care to TB patients (see Preamble). It defines the responsibilities of the public authorities at the national and local levels (art(s). 5, 6, 7, 8) and the activities to be conducted for the detection of patients ill with TB (art. 9) and for the delivery of health care (art. 10). More precisely, it specifies the different instruments used for TB control and care such as obligatory medical screening (art. 9), inpatient and outpatient medical care (art. 10), vaccination (art. 12) or forced hospitalization. No coercive measure is foreseen in the case of a person who refuses to undergo medical screening. According to art. 9 (7), where individuals refuse such screening, they may be barred from work, school, university or practical training.

The law on countering TB completes art. 9 of the law on fundamentals of health care that indirectly prescribes the use of forced hospitalization in the context of TB. TB and HIV/AIDS are defined in Art. 1 (12) of the law on countering TB, as revised, as “a socially dangerous infectious disease caused by mycobacterium tuberculosis”. The law prescribes in art. 11 the legal grounds and the procedural rules for the application of forced hospitalization.

Legal grounds

According to art. 11 of the law on countering TB, a patient with a contagious form of TB who violates the anti-epidemic regimen and therefore poses a risk of infecting other people with TB, shall be hospitalized against his or her will.

Hospitalization is defined in art. 1 as placement in a TB facility with the purpose of diagnosis, treatment or isolation – isolation being the separation of a person with a contagious form of TB from other persons “to prevent the transmission of infection to other persons” as well as for the “provision of medical care and follow up control over adherence to counter-epidemic regimen”.

Art. 1 (6) of the same law defines the anti-epidemic regimen as a set of special measures determined by the central executive body that is responsible for the development and implementation of state policy in the sphere of health and designed for the protection of the population, including the protection of the medical staff. Basically, these measures are rules of behaviour that should be followed by patients with contagious TB.

Procedural rules

The decision to hospitalize a patient without his or her consent, or to prolong such hospitalization, is within the competence of the courts. According to art. 11 of the law on countering TB, a request for a forced hospitalization or for the prolongation of such hospitalization shall be made by the TB facility representative and be based on conclusions by the doctor in charge of the patient. The medical doctor should demonstrate the need for involuntary hospitalization. The request shall be made within 24 hours of the moment of detecting a “violation of the anti-epidemic regimen”. The law on countering TB was complemented by an amendment introduced in the Civil Procedural Code (CPC) by Law No. 4565-VI adopted on 22 March 2012. The court decision must be taken within 24 hours (art. 285 CPC) and executed immediately (art. 286-2 CPC). The local authorities must take measures to protect the property of the person concerned by the court decision (art. 286-3 CPC).

The law on countering TB stipulates that hospitalization shall last three months. Any extension of the three-month period shall be decided by the court on the basis of the documentation established by the doctor directly responsible for the patient. The court decision is directly enforceable.

Specialized TB facility

The law on countering TB does not give clear details concerning the facilities where patients shall be involuntarily hospitalized. Art. 11 states only that these patients shall be involuntarily hospitalized in TB facilities “that have appropriate departments”. Further details are included in Order of the Ministry of Health No. 846 of 9 November 2009 on the organization of medical care for patients with MDR-TB and contagious forms of TB subjected to involuntary hospitalization. This Order mainly enumerates the main tasks to be accomplished within these departments (prevention, diagnosis and treatment) and some conditions to be respected, such as segregation of this department from other departments within the TB hospital, and of the patients from other patients ill with a different strain of TB. No other details are given.

Assessment

Forced treatment

As mentioned above, the forced administration of TB treatment is not foreseen by law: it is not mentioned by the law on public health nor by the law on countering TB. The use of forced treatment as an instrument in the field of TB control and management would, therefore, violate domestic law. This is in accordance with the international and European standards analysed above.

Involuntary isolation/hospitalization

The law on countering TB has not been passed by the constitutional court. There are, however, some difficulties with regard to the guarantees enshrined in the constitution and protected by international and European human rights law.

Legal grounds for forced hospitalization

Art. 11 of the law on countering TB legitimizes involuntary hospitalization in cases when a contagious person does not respect the anti-epidemic regimen. There are two difficulties related to the definitions given by the law with regard to the terms “hospitalization” and “anti-epidemic regimen”.

First, it has been reported that involuntary hospitalization is not used in cases when medical treatment for TB is deemed not possible (M/XDR-TB patients). This practice has been discussed. It relies on the definition of “hospitalization” in the law. It is considered that when it is not possible to offer medical care, neither hospitalization nor isolation should be implemented. On the other hand, a mechanism for involuntary hospitalization designed for the protection of public health and for patients that is not applicable for M/XDR-TB patients is not coherent.

Second, the definition of “anti-epidemic regimen” is both vague and ambiguous and should be clarified. Order of the Ministry of Health No. 684 of August 18 of 2010 On adoption of standards of infection control for TB in health care settings, places of long-term stay and the residence of people living with tuberculosis has been mentioned as helpful for the definition of the “anti-epidemic regimen”, although the standards mentioned by the Order do not offer a clear

definition or a clear list of the measures that should be taken or followed by the patient. These standards are designed for hospitals and centres dealing with TB patients, medical personnel and teachers and students at medical institutions (art. 1 (2)). The patients are indirectly concerned by the definition of measures through these authorities. Moreover, these standards take the form of broad recommendations. For instance, the measures prescribed in art. 7 (2) of the Order are formulated in the form of recommendations: patients living at home with family members should respect recommendations concerning contacts with the family members, the use of respirators and the use of a separate room. These measures cannot be used to justify a court decision to involuntarily hospitalize a patient.

It has been mentioned that a few court decisions relying on the procedure described in art. 11 consider that the patient is more likely to be involuntarily hospitalized if he or she leaves the hospital where he or she is currently and thereby stops the treatment. This interpretation is in accordance with the approach of the National Targeted Social Programme to Fight TB in 2012–2016, which has been adopted as law by Parliament. The programme lists the causes of the high incidence, prevalence and death from TB in Ukraine. It mentions the lack of appropriate facilities for involuntary hospitalization “of persons with contagious forms of tuberculosis who avoid the treatment” as one of the causes of these phenomena.

Measure of last resort

Neither art. 9 of the law on the fundamentals of health care nor art. 11 of the law on countering TB mention that involuntary hospitalization is a last resort measure only to be used in exceptional cases. Neither do these legal provisions mention other less restrictive measures that should be used to help the patient adhere to the treatment regimen and protect the public from the spread of the infection.

The law on countering TB provides only that patients shall have access to health care services and treatment free of charge (art(s). 3, 4)¹⁰ either in an inpatient setting in a TB facility or in an outpatient setting. This law provides solely that patients hospitalized in a TB facility (as opposed to patients receiving treatment on an outpatient basis) shall receive free meals.

Other measures are connected to the reasons why patients refuse to continue treatment. If the reasons for non-adherence are related to poverty, unemployment or lack of family support, involuntary hospitalization is not appropriate to the objectives being legitimately pursued. Non-adherence to treatment might be connected to social conditions that engender difficulties for access to diagnosis and treatment or financial difficulties that prevent payment for transport or for drugs to deal with side-effects.

Representatives of the nongovernmental organizations met during the mission mentioned many reasons for non-adherence to treatment: lack of information concerning the disease and proper treatment; stigmatization and refusal of visits by social workers; rare cases of patients not willing to be registered in a national data bank for personal reasons or hiding from the police; difficulties related to the health care services at TB facilities that do not always offer psychological support or treatment for other diseases or addiction such as alcohol or drug addictions; financial difficulties that prevent the use of private or public means of transport or access to drugs for side-effects; the need to go abroad for seasonal work.

¹⁰ The central executive body responsible for the development and implementation of health care policy has established a list of anti-TB drugs that are provided free to patients.

A list of non-coercive measures could also include material and financial incentives such as hygiene and food packages, specific social services or financial support for the reimbursement of transport costs, access to psychological and social support as well as access to drugs for side-effects free of charge. Specific measures for ex-detainees, who make up a particularly vulnerable group, could also be defined. It was reported during the mission that coordination between the penitentiary system and the civil sector is inadequate, leading to some newly released prisoners being lost to follow-up. A new programme was started in September 2014 to improve the support given mostly through nongovernmental organizations to prisoners after their release. Electronic registration should also contribute to improved identification of the patients and better transfer of the information related to their treatment regimen.

Procedural rules for involuntary hospitalization

Formal measures prior to involuntary hospitalization

The law on countering TB does not prescribe that patients should receive a formal and written warning that they may be detained if they do not comply with the treatment. Art. 10-2 mentions solely that prior to treatment, the patient has to give his or her informed consent to treatment and shall be informed about the necessity to adhere to the treatment. This does not, however, constitute an adequate step prior to the adoption of the decision to detain a patient.

Court decision

Since the 2012 amendment entered into force, there have been 1277 court decisions for involuntary hospitalization of TB patients. Fifty-seven requests for involuntary hospitalization have been rejected. It was not possible to make an analysis of these decisions and of the respective reasoning of the court. It would be very interesting to analyse the reasons why an involuntary hospitalization is accorded or refused.

Representation of the patient

Participation by patients in trials is allowed “except when the person poses a risk of spreading disease”. If the person does not pose a risk of spreading the disease, he or she should not be subjected to forced hospitalization.

The participation of a representative of the person is mandatory (art. 285-2 of the CPC). However, free legal representation has not, so far, been available. Law No. 3460-VI On Free Civil Legal Aid of 2 June 2011 should be applied. Art. 3 of this law states that legal assistance should be free of charge for everyone, but this law is only partially applicable. Moreover, public awareness of the possibility of being represented is only meagre. There should be a mechanism for the automatic designation of a legal representative.

Review

The possibility for the decision to be reviewed during the period of involuntary hospitalization is explicitly foreseen by art. 9 of the law on the fundamentals of health care, which considers that decisions that limit the rights of citizens because of their health condition may be challenged in court. The CPC has not, however, been modified accordingly and nothing specific has been decided by the law. There is no procedure for the release of a patient who is not a threat to public health. Involuntary hospitalization is decided for a period of up to three months on the basis of the conclusions of the physician. Prolongations are decided by the court on the basis of the conclusions transmitted by the same physician.

Facilities

Specific wards are reserved for involuntary hospitalization with 204 beds for the entire country. Various stakeholders have, however, reported that none of these facilities are suitable for the detention of TB patients. So far, the financial arrangements are not clear for the employment of security guards. The wards are not suitable, there are no individual rooms and a strict separation between the patients according to their forms of TB cannot be ensured. The national TB programme 2012–2016 identified the lack of adapted or suitable departments for involuntary hospitalization of persons with contagious forms of TB who avoid treatment as a reason for the inefficiency of the measures adopted. Lack of infection control in TB and health care facilities was also acknowledged in the National Targeted Social Programme to Fight TB in 2012–2016.

Sanctions for not complying with the court decision

As mentioned above, in practice patients might refuse to comply with the court decision and decide to leave the specialized facility, since the facilities are not equipped to force the patients to stay, although the law provides a sanction that can be used for noncompliance with detention in a specialized treatment facility. According to art. 394 of the Criminal Code, “escape from a specialized treatment facility, or on the way to it, shall be punishable by arrest for a term up to six months, or imprisonment for a term up to two years”. Such a mechanism for criminalizing TB patients does not, however, seem to be the appropriate answer for the purpose of protecting the population against the spread of the disease.

Legislative framework on compassionate use for TB treatment

Legislative framework

The legislative framework applicable in Ukraine does not allow for compassionate use programmes. According to art. 9 of the Law On Medicinal Products of 7 May 1996, pharmaceutical products shall be allowed for use in Ukraine after they have been registered by the state.¹¹

A limited list of exceptions to this general rule is provided by the law on medicinal products. These exceptions do not concern drugs under development but drugs that have already been granted a marketing authorization in another country, such as delamanid and bedaquiline for the treatment of MDR-TB.

The exceptions include the import into Ukraine of unregistered drugs for transit (art. 17-3), for preclinical or clinical trials, for registration, for use in exhibitions and conferences and for the medical support of armed units (art. 17-3), for the treatment of orphan diseases (art. 17-6) or for individual use where citizens have bought a small amount of drugs abroad (art. 17-4).

Other exceptions also apply in cases of disasters, catastrophes and epidemic diseases. According to art. 17-5, non-registered medicinal products can be imported in these cases if the documents confirming their registration in other countries are available. The decision to import drugs is taken on a case by case basis by the Ministry of Health.

¹¹ Law of Ukraine No. 124/96-BP of 4 April 1996 On Medicinal Products, as revised by the laws of Ukraine No. 1673-VII of 12 August 2014, No. 1707-VII of 20 October 2014 and No. 77-VIII of 28 December 2014. The most recent version is from 19 June 2016 on the basis of Law of Ukraine No. 1396-VIII of 31 May 2016.

As regards the procedural rules for the import of nonregistered drugs in exceptional cases, the law on medicinal products was revised in 2014 to facilitate rapid access to the specific drugs listed in art. 9-5.¹² These are drugs designed exclusively for the treatment of TB, HIV/AIDS, viral hepatitis, oncology and orphan diseases. The procedure for state registration of these drugs has been simplified so as to allow rapid access. Art. 9-5 reads as follows: “The decision for the registration or refusal of registration of medicinal products designed exclusively for treatment of TB, HIV/AIDS, viral hepatitis, oncology and orphan diseases, and that have been registered in the USA, Switzerland, Japan, Australia, Canada or the EU as a medicinal product, shall be taken in a seven days period”.

Accordingly, a new procedure for the fast registration of specific drugs has recently been adopted. Resolution of the Cabinet of Ministers of Ukraine No. 125 of 18 March 2015 On changes to the state registration (re-registration) of medicinal products modified the procedure for state registration adopted in 2005 (by Resolution of the Cabinet of Ministers of Ukraine No. 376 of 26 May 2005 On approval of state registration (re-registration) of medicinal products and the size of the fee for state registration (re-registration) in order to allow state registration of specific products within seven days, as prescribed by law.

Assessment/perspectives

The adoption of legislative provisions authorizing access to drugs under development for compassionate use has not so far been discussed by the public authorities. Rapid access to medicines for the treatment of specific diseases (such as HIV/AIDS and TB) that have been registered in other countries but not in Ukraine should be facilitated by the simplification of the procedures introduced in the law on medicinal products. The difficulties related to the procurement of and access to drugs that have already received a marketing authorization in Ukraine for all patients constitute a major challenge for the authorities and should be dealt with first.

Recommendations

Use of coercive measures

1. The law on fundamentals of health care should be modified in order to make clear that the forced administration of TB treatment cannot be applied and that the full and well-informed consent of the person is needed before a medical treatment measure is used.
2. The law on countering TB should be revised as follows.
 - A preamble should be introduced in order to reiterate the objectives of the law, namely, the protection of public health as well as the protection of the human rights of the patients. Standards in international and European human rights law could be reiterated as well as the standards defined by WHO's *Guidance on ethics of TB prevention, care and control*.
 - The objective of involuntary hospitalization should be clearly defined as a mechanism to offer medical treatment to TB patients either for the disease or as palliative care.

¹² Law of Ukraine No. 1192-XIV of 22 October 1999 On Humanitarian Aid does not give any details of the procedure to be followed. It focuses on the question of taxation of imported drugs and not on the conditions of quality and safety of the products.

- It should be clearly specified that only persons ill with active TB, who explicitly refuse treatment and are dangerous to others, might be subject to involuntary hospitalization.
- Clear criteria should be established for assessing the explicit refusal of the patient to adhere to treatment.
- Involuntary hospitalization should be clearly established as a measure of last resort that is only to be used in exceptional cases.
- It should be specified that involuntary hospitalization must take place only when it is the appropriate method of attaining the objectives of the treatment for the patient and the protection of the population against the spread of the disease.
- A list of non-coercive measures to be undertaken before involuntary hospitalization is decided upon should be drawn up and adopted. These measures should be capable of being adapted to offer appropriate answers to the medical, economic or social difficulties that cause non-adherence to treatment. They should take into account, more particularly, the age of the patient, his or her professional activities and family responsibilities, his or her coinfection status or addiction to drugs or alcohol, and finally his or her status as an ex-detainee or a homeless person.
- As regards the procedural rules designed to ensure that decisions for involuntary or continued hospitalization are reviewed, the following amendments should be included.
 - Explicit provision should be made for the person concerned to be informed about the consequences of his or her refusal to continue the treatment.
 - The reasons for non-adherence to treatment and the efforts made to help the patient overcome his or her difficulties and adhere to the treatment regimen should be documented and presented to the court, including the reasons why less restrictive measures were not sufficient in that specific case.
 - It should be made explicit that persons threatened with involuntary hospitalization or persons who are already hospitalized against their will shall benefit from the due process protection clause, including having access to free legal representation.
 - The law should be more coherent. A patient posing a threat to public health should not be able to appear and represent himself in court.
 - It should be made explicit that persons who are hospitalized against their will shall enjoy all fundamental rights guaranteed under domestic, European and international law and, more specifically, the rights to life, to privacy, to family life, to data protection and confidentiality.
 - The conditions for reviewing decisions to enforce involuntary hospitalization should be more precise and a regular review of these decisions should be introduced. When the criteria for involuntary hospitalization are no longer met, the grounds for it no longer exist. There should be a discussion as to whether a patient who is no longer contagious but who poses a threat and still needs to continue treatment should or should not be released. Evidence of compliance with treatment measures should be taken into account and should weigh strongly in favour of ending detention.
- The following elements regarding involuntary hospitalization facilities should be included in the law. The conditions of hospitalization must be appropriate. A patient shall not be hospitalized in a department under conditions where he or she might be infected with another strain of TB. The public authorities should make sure that the facilities used for

involuntary hospitalization are adapted to the treatment of these patients and respect infection control precautions. Patients with various forms of TB should be kept separated. The importance of protecting individuals from developing additional drug resistance and the respect for all fundamental rights should be mentioned.

- The capacities for palliative care in hospital settings should be developed.
3. More research should be encouraged and conducted with the aim of ensuring the efficient protection of patients' rights in accordance with international and European human rights standards. The Parliamentary Commissioner for Human Rights should be called upon by the national deputies to exercise his or her functions, conduct inspections and report on the protection of TB patients by relevant bodies of the state or local authorities.

Access to drugs for M/XDR-TB patients

4. The possibilities offered by the legislative framework on the rapid import of new drugs (such as delamanid and bedaquiline) that have been authorized in the country of origin but not in Ukraine should be used as soon as possible so as to offer M/XDR-TB patients an alternative treatment. Delamanid and bedaquiline have received a marketing authorization in other countries (particularly in the European Union and the United States of America).
5. The possibility should be discussed of introducing, under certain circumstances, a mechanism allowing access for compassionate use to drugs that are under development.

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Annex 1

SCHEDULE AND PEOPLE MET DURING THE MISSION

Monday 20 April 2015

Ministry of Health

Mr Oleksandr Pravylo, Acting Head, Legal Department

Ministry of Justice

Ms Svitlana Ryaboshapka, Deputy Head, Department of Constitutional, Administrative and Social Law

Tuesday 21 April 2015

State Service of Ukraine on Pharmaceuticals

Mr Viktor Kasyanenko, Head, Department of Production Certification

Mr Konstantin Romanenko, Head, Department of Pharmaceutical Safety Surveillance

Mr Yurii Pogrebnyak, Deputy Head, Department of European Integration and External Relations

Ms Iryna Fedenko, Head, Department of European Integration and External Relations

National Red Cross Society

Mrs Alla Habarova, Secretary-General

All-Ukrainian Board on Patients' Rights and Security Protection

Dr Viktor Serdiuk, President

Wednesday 22 April 2015

National Commissioner for Human Rights (Ombudsman)

Mr Dmytro Lyah, Head, Directorate of Socioeconomic and Humanitarian Rights Adherence

Ms Pistryak Daria, Head, Socioeconomic Rights Adherence Department, Directorate of Socioeconomic and Humanitarian Rights Adherence

Ms Valentyna Obolentseva, Expert, Division of Expertise and Analysis of Medical Issues, Directorate of Implementation of the National Preventive Mechanism

UCDC, National TB Programme (Global Fund to fight HIV/AIDS, tuberculosis and malaria recipient principal recipient)

Professor Natalia Nizova, Director, NTP Manager

Dr Olga Pavlova, Deputy Head in charge of TB Control

Dr Yana Terleeva, Specialist on TB Control

Dr Oleg Masiuk, Specialist on TB Control

Dr Olena Diuzheva, Specialist on TB Control

Office of the United Nations High Commissioner for Human Rights

Mr Marc Bojanic, Human Rights Officer

Ms Nataliya Pylypiv, National Human Rights Officer

Thursday 23 April 2015

Centre of expertise (Regulatory Authority on Pharmaceuticals)

Ms Tetyana Dumenko, Director, Department of Rational Pharmacotherapy and Support of State
Formulary System

Ms Olena Matveeva, Director, Department of Pharmacovigilance

Ministry of Social Affairs

Ms Tetyana Plahotnik, Specialist, International Department

Ms Iryna Tarasiuk, Head, Division of Services to Homeless People and Other Risk Groups,
Department for Elderly People and Social Services

Ms Viktoriya Sanovska, Head, Division for Prevention of Socially Dangerous Diseases,
Department of Social Orphanage Prevention

HIV/AIDS Alliance (Global Fund to fight HIV/AIDS, tuberculosis and malaria recipient)

Dr Evgenia Gelyukh, TB expert

*All-National Network of People Living with HIV (Global Fund to fight HIV/AIDS, tuberculosis
and malaria recipient)*

Ms Angela Skopenko, Head, Grants Management Department

Mr Gennadiy Golobokov, Consultant

Ms Valentyna Obolentseva, Consultant

WHO Country Office

Dr Andrej Slavuckij, TB, MDR-TB Medical Officer

Parliamentary Committee on Health

Dr Iryna Semerun', Deputy Head, Secretariat

Dr Svitlana Zbrozhek, Adviser to the Secretariat