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PREMIÈRE SECTION

CEDH-LF4.8R
IB/nni

Strasbourg, le 24 février 2015

Requêtes concernées:
58502/11 ABDYUSHEVA c. Russie
55483/13 ANOSHKIN c. Russie

Maître,

Le Gouvernement m'a fait parvenir une traduction en anglais de ses observations relatives aux requêtes susmentionnées.

Vous trouverez ci-joint, pour votre information, un exemplaire de cette traduction.

Veuillez agréer, Maître, l'assurance de ma considération distinguée.

Søren Nielsen
Greffier de section

P.J.

**УПОЛНОМОЧЕННЫЙ РОССИЙСКОЙ ФЕДЕРАЦИИ
ПРИ ЕВРОПЕЙСКОМ СУДЕ ПО ПРАВАМ ЧЕЛОВЕКА –
ЗАМЕСТИТЕЛЬ МИНИСТРА ЮСТИЦИИ РОССИЙСКОЙ ФЕДЕРАЦИИ**

Representative of the Russian Federation at the European Court of Human Rights – deputy Minister of Justice of the Russian Federation

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« 10 » February 20 15

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Mr Søren NIELSEN
First Section Registrar

European Court of
Human Rights

Applications concerned
62964/10 Kurmanayevskiy v. Russia
58502/11 Abdyusheva v. Russia
55683/13 Anoshkin v. Russia

Dear Sir,

With reference to your letter of 11 December 2014, please find attached a copy of the English translation of the Memorandum of the Government of the Russian Federation on the above applications.

Yours faithfully,

Georgy Matyushkin

Encl.

24 November 2014
16-5805-14

**EUROPEAN COURT
OF HUMAN RIGHTS**

MEMORANDUM
Applications
no. 62964/10 Kurmanayevskiy v. Russia
no. 58502/11 Abdyusheva v. Russia
no. 55683/13 Anoshkin v. Russia

On 14 May 2014 the European Court of Human Rights informed the Government of the Russian Federaiton of applications nos. 62964/10 *Kurmanayevskiy v. Russia*, 58502/11 *Abdyusheva v. Russia*, 55683/13 *Anoshkin v. Russia*, lodged under Article 34 of the European Convention for the

Protection of Human Rights and Fundamental Freedoms by Russian nationals Aleksey Vladimirovich Kurmanayevskiy, Irina Nikolayevna Abdyusheva and Ivan Vasilyevich Anoshkin.

The European Court, in compliance with Rule 54 § 2 (b) of its Rules, invited the Government of the Russian Federation to submit their comments and answer the following questions.

1. Was there a violation of the applicants' right to respect for their private life guaranteed by Article 8 of the Convention (*Shtukaturov and Others v. Bulgaria*, nos. 47009/11 and 35872 of 13 November 2012, §§ 116-26 (extracts))? In particular:

a) Does the absolute ban on drug addiction treatment by substitution therapy using methadone and buprenorphine in the Russian Federation provide for fair balance between the State's obligation to protect the life and health of the persons under its jurisdiction, by way of regulation of access to narcotic substances, on the one part, and the applicants' interest in access to the medicines which could help their cure of drug addiction, on the other part?

b) What were the reasons for absolute ban on substitution therapy treatment method in the Russian Federation?

2. Were the applicants subjected to discrimination in connection with their health state (*Kiyutin v. Russia*, no. 2700/10 of 10 March 2011, § 57) in violation of Article 14 of the Convention, taken in conjunction with Article 8 of the Convention, in connection with a ban on drug addiction treatment using methadone and buprenorphine, as provided for by Article 31 §§ 1, 6 of the Federal Law *On Narcotic Drugs and Psychotropic Substances*?

Contents

1. Circumstances of the cases

Application of Aleksey Vladimirovich Kurmanayevskiy (no. 62964/10)

A.V. Kurmanayevskiy applied to the Sovietskiy District Court of the city of Kazan with a claim against State Autonomous Healthcare Institution "Republican Narcological Dispensary of the Ministry of Healthcare of the Republic of Tatarstan" (hereinafter - GAUZ "RND MZ RT") requesting to recognize his right for treatment by substitution methadon therapy.

To justify his claims A.V. Kurmanayevskiy indicated that since 1997 he had been registered with GAUZ "RND MZ RT" with the diagnosis "psychotic behavioural disorders resulting from taking opioids, dependence syndrome", and since 2001 he had been registered with GUZ "Republican Centre for Prevention and Controlling AIDS and Infectious Diseases" with the diagnosis "V-20" (HBV) and "V-17" (Hepatitis C). He has been taking heroin since 1995. He has been treated from drug addiction in GAUZ "RND MZ RT" 19 times, the latest time in 2010.[1] In 1999 there was a 7-months remission.

[1] In his application the applicant alleges that he had been ill-treated by the medical personnel of the narcological dispensary. In this connection, based on the information received from the Ministry of Healthcare of the Republic of Tatarstan, the authorities of the Russian Federation note that A.V. Kurmanayevskiy applied for medical aid on his own will, and if the patient refused to continue in-patient treatment he was discharged from GAUZ "Republican Narcological Dispensary" of the Ministry of Healthcare of the Republic of Tatarstan. There were no complaints lodged by A.V. Kurmanayevskiy concerning provision of medical aid, application of measures of physical restrain in the conditions of GAUZ

In December 2010 A.V. Kurmanayevskiy applied to GAUZ "RND MZ RT" with a request to put him on substitution methadone therapy, referring to recommendations of WHO, UN Office on Drugs and Crime, the Joint United Nations Programme on HIV/AIDS, and stating that the standards of drug addiction treatment in the Russian Federation were contrary to the scientific ideas of the mechanisms of appearance of drug addiction and different from the medical treatment standards adopted by WHO and international medical associations.

On 26.01.2011 A.V. Kurmanayevskiy's application was examined at the meeting of the medical commission of GAUZ "RND MZ RT". The commission dismissed his application due to legislative ban on use of substitution methadone therapy method in the Russian Federation.

The Sovietskiy District Court of the city of Kazan found the refusal of GAUZ "RND MZ RT" to prescribe A.V. Kurmanayevskiy medical treatment by the method of substitution methadone therapy lawful and reasonable.

The court noted that A.V. Kurmanayevskiy's reference to the recommendations of WHO in the part of application of such method of drug addiction treatment in this case did not constitute grounds for satisfaction of the claim as the said recommendations were stated in the document named Position Paper of WHO/UNODC/UNAIDS and were actually of advisory nature. The Position Paper contains a proposal to use substitution therapy method, including methadone therapy, together with other methods of drug addiction treatment.

By force of Article 54 § 1 of the Federal Law *On Narcotic Drugs and Psychotropic Substances* the State guarantees to people addicted to drugs rendering narcological aid which includes medical examination, consultation, diagnostics, medical treatment and medical and social rehabilitation.

In compliance with Article 55 of the Federal Law *On Narcotic Drugs and Psychotropic Substances*:

1. Diagnostics of drug addiction, medical examination, consulting and medical and social rehabilitation of drug addicted persons shall be effected in institutions of state, municipal or private healthcare systems which have obtained a license for the said type of activity in the procedure established by the laws of the Russian Federation.

2. Treatment of drug addicted persons shall be effected only in institutions of state and municipal healthcare systems.

"Republican Narcological Dispensary" of the Ministry of Healthcare of the Republic of Tatarstan. No facts of using physical restraint methods have been registered in medical documents. A.V. Kurmanayevskiy's submissions that "in the process of rendering medical aid he was tied to the bed by his arms and legs with special belts", "after every hospitalisation for detoxication the applicant had large bruises on his arms and legs, and several times he had joints dislocations" are not true.

4. Diagnostics of drug addiction and treatment of drug addicted persons shall be effected by means and methods allowed by the federal executive authority in the sphere of healthcare.

Methadone is among the drug substances prohibited for circulation in the Russian Federation.

Consequently, as the court ruled, medical treatment for drug addiction using a narcotic drug prohibited for circulation can not be applied and prescribed to A.V. Kurmanayevskiy.

The Sovietskiy District Court of the city of Kazan by its decision of 07.06.2011 dismissed A.V. Kurmanayevskiy's claim against GAUZ "RND MZ RT" as regards recognizing his right to treatment by substitution methadone therapy method (a copy of the decision is attached to the present Memorandum).

On 11.07.2011 the Judicial Division for Civil Cases of the Supreme Court of the Republic of Tatarstan by its cassational ruling (a copy of which is attached to the present Memorandum) upheld the decision of the Sovietskiy District Court of the city of Kazan of 07.06.2011 in this case.

In the said cassational ruling it is noted that "as rightly noted by the trial court, methadone is referred to narcotic substances prohibited for circulation in the Russian Federation, therefore the trial court had no legal grounds for taking a decision on prescribing the applicant medical treatment for drug addiction using a narcotic substance prohibited for circulation.

Based on the aforementioned grounds the plaintiff's arguments contained in the cassational appeal regarding the fact that the State is obliged to take all the necessary measures to guarantee realization by the citizens of all their constitutional rights, including the right to receive the necessary treatment by the method indicated by the plaintiff, shall be dismissed as invalid.

Other allegations in the complaint of unsuccessful attempts to treat him for drug addiction by any other means, the aims of methadone therapy to normalise patient's narcological condition, the principles of selection for participation in the "substitution therapy" programmes on the basis of patient's multiple failures to get rid of opioid dependence, equally can not serve as the grounds for quashing the court's decision, as the said treatment method is not used in the Russian Federation".

Application of Irina Nikolayevna Abdyusheva (no. 58502/11)

On 03.05.2011 I.N. Abdyusheva applied to the Leningradskiy District Court of Kaliningrad with a statement challenging the actions of the Ministry of Healthcare of the Kaliningrad Region as regards refusal to prescribe her medical treatment by opioid substitution (supporting) therapy using methadone or buprenorphine.

The applicant submitted that the Ministry of Healthcare of the Kaliningrad Region, in reply to her application of 11.01.2011 (a copy of which is attached to

this Memorandum) refused to prescribe her medical treatment by opioid substitution (supporting) therapy using methadone or buprenorphine.

The refusal was stated, on behalf of the Ministry of Healthcare of the Kaliningrad Region, in the letter of the Chief Doctor of OGBUZ "Regional Narcological Hospital" of 27.01.2011, *ref.* no. 172 (a copy of the letter is attached to this Memorandum) where as the indicated reason for the refusal was named the ban for treatment of drug addiction using methadone and buprenorphine in the territory of the Russian Federation, in compliance with the Federal Law of the Russian Federation of 08.01.1998 no. 3-FZ *On Narcotic Drugs and Psychotropic Substances*.

In substantiation of her statement, I.N. Abdyusheva referred to the fact that she was taking opiates from February 1984 and has been registered as a drug addict since 20.04.1984. On 18.07.1984 she was diagnosed with "abuse of opiate drugs". She was regularly treated for drug addiction in various clinics and by all methods of drug addiction treatment practised in the USSR (and subsequently in Russia), both in correctional and civil medical institutions in various regions of the country, twice she underwent treatment for drug addiction in prisons, she underwent compulsory treatment for drug addiction, but lapsed back into taking drugs again. The treatment did not bring any long-time remission.

The Leningradskiy District Court of Kaliningrad by its decision of 27.05.2011 dismissed I.N. Abdyusheva's application as regards challenging the actions of the Ministry of Healthcare of the Kaliningrad Region (a copy of the decision is attached to this Memorandum).

The Judicial Division for Civil Cases of the Kaliningrad Regional Court by its cassational[2] ruling of 03.08.2011 (a copy of which is attached to this Memorandum) upheld the district court's decision.

In the cassational[3] procedure the case was not examined, as the Leningradskiy District Court of the city of Kaliningrad by its ruling of 24.04.2012 upheld by the appellate ruling of 29.05.2012 (copies are attached to this Memorandum), refused the applicant's request to restore the missed procedural time-limit for lodging a cassational appeal.

Refusing to satisfy the lodged claims and stating the detailed legal reasoning in the decision and the cassational ruling, the judicial authorities based on the fact that the valid Russian legislation prohibits treatment for drug addiction in the territory of the Russian Federation using methadone and buprenorphine.

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[2] In compliance with the *valid* provisions of the Code of Civil Procedure of the Russian Federation ("the CCivP RF").

[3] In compliance with the provisions of the CCivP RF, which came into force on 01.01.2012, on the *procedure of review of final court decisions* (Federal Law of 09.12.2010 no. 353-FZ *On Amendments to the Code of Civil Procedure of the Russian Federation*).

In addition, during examination of the case there were assessed the applicant's arguments that the ban on use of methadone or buprenorphine for treatment for drug addiction did not comply with the provisions of the international treaties of the Russian Federation. The court based on the fact that the provisions of the Russian legislation in the part concerning the ban on use of the above-mentioned means for treatment for drug addiction still comply with the provisions of international treaties including the Single Convention on Narcotic Drugs of 1961.

Application of Ivan Yurievich Anoshkin (no. 35683/12)

On 28.08.2012 the Central District Court of the city of Togliatti of the Samara Region accepted for proceedings the statement of I.V. Anoshkin as regards challenging the actions of the Ministry of Healthcare and Social Development of the Samara Region which were expressed in the refusal to prescribe the applicant medical treatment for drug addiction by the method of opioid substitution (supporting) therapy using methadone or buprenorphine.

As the reasoning for the statement it was indicated that I.V. Anoshkin had been using opiates (heroin, dezomorphine, acetylated opium) since 1994, was registered as a drug addicted person diagnosed with "opioids dependance syndrome". He tried to cure twice however he had to interrupt the treatment due to negative attitude to him on the part of doctors and paramedics.

On 17.04.2012 I.V. Anoshkin sent to the Ministry of Healthcare and Social Development of the Samara Region an application requesting to prescribe him the method of opioid substitution (supporting) therapy using methadone or buprenorphine.

On 16.05.2012 the Ministry of Healthcare and Social Development of the Samara Region by its letter refused to prescribe the applicant medical treatment for drug addiction by the method of opioid substitution (supporting) therapy using methadone or buprenorphine in connection with the ban on treatment for drug addiction using these drugs in the territory of the Russian Federation.

I.V. Anoshkin believed that this refusal created obstacles for exercising his constitutional right to medical aid, therefore he requested to recognize the actions of the Ministry of Healthcare and Social Development of the Samara Region, expressed in the refusal to prescribe the applicant drug addiction treatment by the method of opioid substitution (supporting) therapy using methadone or buprenorphine, unlawful and to oblige them to prescribe the said treatment for the applicant.

The Central District Court of the city of Togliatti of the Samara Region by its decision of 07.11.2012 dismissed I.V. Anoshkin's application as regards challenging the actions (omission) of the state authority and prescribing the said treatment.

The Samara Regional Court by its appellate ruling of 05.02.2013 upheld the decision of the Central District Court of the city of Togliatti of the Samara Region of 07.11.2012 and dismissed I.V. Anoshkin's appeal.

The judge of the Samara Regional Court by the ruling of 05.09.2013 refused to submit I.V. Anoshkin's cassational appeal against the decision of the Central District Court of the city of Togliatti of the Samara Region of 07.11.2012 and the appellate ruling of the Judicial Division for Civil Cases of the Samara Regional Court of 05.02.2013 for examination at the court session of the Presidium of the Samara Regional Court.

I.V. Anoshkin challenged the actions of the Ministry of Healthcare and Social Development of the Samara Region, which were expressed in refusal to prescribe him drug addiction treatment by the method of opioid substitution (supporting) therapy using methadone or buprenorphine.

In compliance with Article 254 § 1, Article 258 § 4 of the Code of Civil Procedure of the Russian Federation any individual or entity has the right to challenge in court a decision, action (omission) of a state authority, local self-government authority, official, state or municipal employee if they believe that their rights and freedoms have been violated.

The court dismisses an application if it establishes that the challenged decision or action has been taken or effected in compliance with the law within the competencies of a state authority, local self-government authority, official, state or municipal employee, and the individual's rights or freedoms have not been violated.

On 17.04.2012 I.V. Anoshkin sent to the Ministry of Healthcare and Social Development of the Samara Region an application regarding the possibility to prescribe him the method of opioid substitution (supporting) therapy using methadone or buprenorphine. In compliance with the reply from the Ministry of Healthcare and Social Development of the Samara Region of 16.05.2012 it was explained to I.V. Anoshkin that according to Federal Law of 08.01.1998 no. 3-FZ *On Narcotic Drugs and Psychotropic Substances* **treatment** for drug addiction by narcotic drugs and psychotropic substances introduced in Schedule II, where buprenorphine is included, **is prohibited in the Russian Federation**. Methadone is included in Schedule I of the List of Narcotic Drugs prohibited for circulation in the Russian Federation.

In compliance with Article 7 §§ 2 and 3 of Federal Law of 21.11.2011 no. 323-FZ *On the Fundamental Principles of Protection of the Health of the Citizens in the Russian Federation* the procedure of rendering medical aid and medical aid standards are approved by the duly authorized federal executive authority.

The procedure of rendering medical aid is elaborated as per its separate types, profiles, diseases or conditions (groups of diseases or conditions) and includes: stages of medical aid rendering; rules of organization of the activities

of a medical institution (its structural subdivision, doctor); other provisions, based on the specific characteristics of rendering medical aid.

In compliance with Article 2 of Federal Law of 08.01.1998 no. 3-FZ *On Narcotic Drugs and Psychotropic Substances* narcotic drugs, psychotropic substances and their precursors subject to control in the Russian Federation shall be included in the *List of Narcotic Drugs, Psychotropic Substances and their Precursors subject to Control in the Russian Federation*, and, depending on the applied State control measures, shall be entered in the following lists:

1. the list of narcotic drugs, psychotropic substances and their precursors the circulation of which is prohibited in the Russian Federation in compliance with the Russian legislation and international treaties of the Russian Federation (Schedule I);

2. the list of narcotic drugs and psychotropic substances the circulation of which is limited in the Russian Federation and in respect of which the control measures have been established in compliance with the Russian legislation and international treaties of the Russian Federation (Schedule II).

Methadone is included in Schedule I and buprenorphine is included in Schedule II.

Article 31 §§ 1 and 6 of Federal Law of 08.01.1998 no. 3-FZ *On Narcotic Drugs and Psychotropic Substances* provides that narcotic drugs and psychotropic substances included in Schedules II and III may be used for medical purposes, however medical treatment for drug addiction by the narcotic drugs and psychotropic substances included in Schedule II is prohibited in the Russian Federation.

Based on the aforementioned the court concluded that there were no legal grounds for satisfaction of the claim lodged by I.V. Anoshkin as regards challenging the actions of the Ministry of Healthcare and Social Development of the Samara Region expressed in the refusal to prescribe the applicant medical treatment for drug addiction by the method of opioid substitution (supporting) therapy using methadone or buprenorphine.

2. As regards inadmissibility of A.V. Kuznetsovskiy's application under Article 35 § 1 of the Convention due to non-exhaustion of effective domestic remedies prior to applying to an international court

In compliance with Article 35 § 1 of the Convention the European Court may only deal with the matter after all domestic remedies have been exhausted, according to the generally recognized rules of international law, and within a period of six months from the date on which the final decision in the case was taken by national authorities.

The rule of exhaustion of domestic remedies usually requires that "the complaints intended to be made subsequently at international level should have

been aired before «domestic courts», at least in substance and in compliance with the formal requirements and time-limits laid down in domestic law" (see, among others, *Gladkikh v. Russia*, no. 18870/04, decision of 25.09.2008).

In A.V. Karmanayevskiy's application (§ 16) it was indicated that «**there was no domestic decision on the merits of the applicant's complaint, the applicant did not apply to national judicial authorities as he believed such application to be ineffective**», and that «the circumstances of the applicant's specific case allowed to state that due to the direct statutory ban on use of opioid substitution therapy in Russia the application to the court in Russia as a domestic remedy would be ineffective in the applicant's case».

Though **later, after lodging the application with the Court (i.e. post factum)**, the applicant applied to the national courts (see the decision of the Sovietskiy District Court of Kazan of 07.06.2011, the cassational ruling of the Judicial Division for Civil Cases of the Supreme Court of the Republic of Tatarstan of 11.07.2011), as follows from the aforementioned A.V. Karmanayevskiy **has not exhausted all domestic remedies prior to application to the international court. Thus, in A.V. Karmanayevskiy's case the condition of admissibility of application provided for by Article 35 of the Convention was violated.** A.V. **Karmanayevskiy's arguments regarding "ineffectiveness" of applying to court for restoration of his violated rights appear even more unconvincing against the background of 2 other examined applications where the applicants have exhausted domestic remedies prior to applying to the international court. In view of the aforementioned, the Government of the Russian Federation maintain that A.V. Karmanayevskiy's application is absolutely inadmissible.**

In view of the aforementioned the Government of the Russian Federation declare A.V. Karmanovskiy's application inadmissible under Article 35 § 1 of the Convention.

3. Answer to question no. 1 posed by the Court

Was there a violation of the applicants' right to respect for their private life guaranteed by Article 8 of the Convention (Stanislav and Others v. Bulgaria, nos. 46039/11 and 358/12 of 13 November 2012, §§ 116-26 (extracts))? In particular:

a) Does the absolute ban on drug addiction treatment by substitution therapy using methadone and buprenorphine in the Russian Federation provide for fair balance between the State's obligation to protect the life and health of the persons under its jurisdiction, by way of regulation of access to narcotic substances, on the one part, and the applicants' interest in access to the medicines which could help their cure of drug addiction, on the other part?

b) What were the reasons for absolute ban on substitution therapy treatment method in the Russian Federation?

In connection with question no. 1 posed by the European Court the Government of the Russian Federation state that **there is no violation of the applicants' right to respect for their private life guaranteed by Article 8 of the Convention in the present cases.**

We present the following arguments and information in substantiation of our position.

As regards the reasons which have served as the basis for absolute ban on practices by the method of substitution therapy using methadone and buprenorphine in the Russian Federation

On legislative regulation of turnover, measures for control in respect of narcotic drugs, including methadone and buprenorphine, in the Russian Federation

Drug addiction (dependence syndrome) is classified among **mental disorders/psychotic disorders and behavioural disorders** related to use of psychoactive substances (in this case - narcotic substances) included in Class V "Mental and Behavioural Disorders" (Codes F11-F16, F19) of the International Statistical Classification of Diseases and Health Problems of 10 edition (§ 4.3. of the Order of the Ministry of Healthcare of Russia of 27.05.1997 no. 170, amended as of 12.01.1998 *On Adoption of the International Statistical Classification of Diseases and Health Problems of 10 edition by Healthcare Authorities and Institutions of the Russian Federation*).

Methadone[4] and buprenorphine are narcotic drugs of opioid group, the use of which causes mental and behavioural disorders (drug addiction, dependence syndrome, withdrawal state, etc.) (Code F11).

Use of methadone and buprenorphine in case of drug addiction caused by taking other opioids (opium, heroin, etc.) **increases the aforementioned mental and behavioural disorders. At the same time, the risk of lethal overdoses is increased** (see more details below in the section «*On mortality as the result of taking drugs among participants of substitution therapy programmes in Europe*» of this Memorandum).

Using the narcotic drugs methadone and buprenorphine in case of drug addiction caused by taking other narcotic substances (Codes F12-F16) leads to development of poly-drug use (Code F19). In addition, mental and behavioural disorders deepen as well.

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[4] Methadone was synthetically produced in Germany during World War II due to absence of morphine, and it was given the name "adolphine". See: E.A. Babayan. Use of methadone can not be regarded as treatment // Narkozu Agenku. 2002. No. 3. P. 19-22.

Thus, **replacement of other narcotic drugs by methadone and buprenorphine must be regarded not as a method for treatment for drug addiction but as legalisation of drug abuse.**

In the USSR, after scientific discussion, taking into consideration the pharmacological peculiarities of the effect on human organism methadone (phenadone) was excluded from the list of medicines and prohibited for use (Order of the Ministry of Healthcare of the USSR of 15.04.1977 no. 336). In the Order of the Minzdravsotsprom (Ministry of Healthcare and Medical Industry) of Russia of 14.08.1995 no. 239 *On Additional Measures for Control of Narcotic Drugs, Highly Potent and Poisonous Substances* it is noted: "To confirm the earlier established procedure prohibiting application of narcotic drugs for therapeutic purposes for treatment for drug addiction, including handing over to persons suffering from drug addiction of narcotic drugs ("narcotic ration") in any form (giving prescription, prescribing in a hospital, dispensary, *etc.*)".

The Russian Federation, in compliance with the Single Convention on Narcotic Drugs of 1961 (hereinafter - "the Single Convention of 1961") **has assumed the obligation to take in its territory any special control measures in respect of narcotic drugs which are necessary in its opinion, as well as to introduce legislative and administrative measures necessary for compliance with the Single Convention of 1961** (subparagraphs "a", "b" of § 5 of Article 2, § "a" of Article 4).

Methadone, in view of especial dangerousness of its properties for human health, is included in List of Drugs included in Schedule I, approved by the Single Convention of 1961,[1] and due to this its circulation must be controlled by the most severe measures, prescribed by both international and national legal provisions.

Simultaneously, **in compliance with Article 39 of the Single Convention of 1961, notwithstanding anything contained in this Convention, a Party shall not be, or be deemed to be, precluded from adopting measures of control more strict or severe than those provided by**

[1] "In 1961, when the Single Convention was being drawn up and adopted, the opinion that methadone was a narcotic drug as dangerous as morphine and heroin was undisputed. In accordance with this, methadone was included in List of Drugs included in Schedule I of the Single Convention on Narcotic Drugs of 1961. In this period the supporters of use of methadone based on the fact that the drug was actually proposed for treatment for the most serious form of drug addiction - heroin addiction, and that control over distribution of narcotic drugs would provide the possibility to regulate taking by heroin addicts of methadone instead of heroin with subsequent termination of giving methadone. However, as proved by the practice, using methadone quickly led to creation of a new group of drug addicts using only methadone" (See: E.A. Babayan: Use of methadone can not be regarded as treatment // Novaya Aptetka. 2002. No. 3. P. 19-22).

this Convention and in particular from requiring that Preparations in Schedule III of the Single Convention of 1961 or drugs in Schedule II of the Single Convention of 1961 be subject to all or such of the measures of control applicable to drugs in Schedule I of the Single Convention of 1961.

In compliance with the Convention on Psychotropic Substances of 1971 (hereinafter - "the Convention of 1971") the Russian Federation assumed the obligation to limit use of the substances included in Schedules II, III, IV of the Convention of 1971, by such means as it may deem reasonable.

As buprenorphine is included in Schedule III of the Convention of 1971, its circulation should be subject to the relevant control measures stipulated both by international and national legal provisions.

The State Anti-Drug Policy Strategy of the Russian Federation till 2020, approved by the Decree of the President of the Russian Federation of 09.06.2010 no. 690, provides for decreasing demand for narcotic drugs by improvement of the system of preventive, medical and rehabilitation work, the system of rendering narcological medical aid to persons suffering from drug addiction and their rehabilitation. The strategic aim of the State policy in the sphere of narcological medical aid development is timely identification and treatment of persons using drugs illegally, improvement of narcological medical aid to drug addicted persons, increasing of availability and quality of such aid and decreasing mortality level. Moreover, subparagraph "d" of § 32 of this Decree explicitly provides for exclusion of using in the Russian Federation of substitution methods of drug addiction treatment using narcotic drugs and psychotropic substances included in Schedules I and II of the List of Narcotic Drugs as well as legalisation of use of particular drugs for non-medical purposes.

In the Russian Federation the legal foundations of the State policy in the sphere of circulation of narcotic drugs, psychotropic substances and their precursors as well as in the sphere of suppression of their unlawful circulation for the purposes of preservation of the citizens' health, state and public safety are stipulated by Federal Law of 08.01.1998 no. 3-FZ *On Narcotic Drugs and Psychotropic Substances* (hereinafter - "Law no. 3-FZ").

In compliance with Article 1 of Law no. 3-FZ narcotic drugs are substances of synthetic or natural origin, drugs included in the *List of Narcotic Drugs, Psychotropic Substances and their Precursors subject to Control in the Russian Federation*, in compliance with the laws of the Russian Federation, international treaties of the Russian Federation, including the Single Convention on Narcotic Drugs of 1961.

By force of Article 2 § 1 of Law no. 3-FZ narcotic drugs, psychotropic substances and their precursors subject to control in the Russian Federation shall be included in the *List of Narcotic Drugs, Psychotropic Substances and their Precursors subject to Control in the Russian Federation* (hereinafter - "the

List"), and, depending on the applied state control measures, entered in the relevant lists.

In compliance with Article 2 § 2 of Law no. 3-FZ, on 30.06.1998 the Government of the Russian Federation issued Decree no. 681 by which it approved the List, and methadone was included in Schedule I of this List and buprenorphine - in Schedule II of the List.

Moreover, circulation of the narcotic drugs included in Schedule I of the List is prohibited in compliance with the legislation of the Russian Federation and international treaties of the Russian Federation, except for the cases stipulated by §§ 3 and 5 of Article 14 of Law no. 3-FZ.

Circulation of the narcotic drugs included in Schedule II of the List is limited and subject to control measures in compliance with the laws of the Russian Federation and international treaties of the Russian Federation (Article 2 § 1 of Law no. 3-FZ).

Therefore, methadone is prohibited for circulation including use (application) for medical purposes, including substitution therapy, and buprenorphine is limited in circulation and subject to control measures.

Thus, buprenorphine is a medical narcotic drug which has undergone State registration and has been included in the Register of Medicines, has established procedures of storage, recommendations and prescription.

However, it is worth noting that in compliance with Article 31 § 6 of Law no. 3-FZ treatment for drug addiction by the narcotic drugs included in Schedule II of the List, including buprenorphine, is prohibited in the Russian Federation.

In view of the aforementioned legislative provisions of the Russian Federation, the medical institutions as well as the courts of the Russian Federation have reasonably and lawfully refused the applicants A.V. Karmanzhovskiy, I.N. Abdyushova and I.V. Anokhin medical treatment for drug addiction by "substitution therapy" method using methadone and buprenorphine.

In addition, **in § 1 of Resolution II «Treatment of drug addicts», adopted by the UN Conference for adoption of the Single Convention on Narcotic Drugs**, which was held in the United Nations Headquarters from 24 January to 25 March 1961, **it was stated that one of the most effective methods of treatment for addiction was treatment in a hospital institution having a drug free atmosphere.**

The Government of the Russian Federation note that **absolute ban** on drug addiction treatment by the method of substitution therapy using methadone and buprenorphine **was established** in the Russian Federation **in connection with the State's obligation to protect the health and lives of the people under its jurisdiction**, by regulation of access to narcotic drugs (see for details about the reasons in this Memorandum).

As regards international acts of advisory nature concerning treatment for drug addiction by substitution therapy method using methadone and buprenorphine, the Government of the Russian Federation would like to note the following:

Basing on the provisions of Chapter X of the UN Charter, UN Economic and Social Council is not vested, in principle, with the authority to take decisions which are legally binding for the Member States. This refers, in particular, to the concluding observations of the Committee on Economic, Social and Cultural Rights adopted on 01.06.2011 at the 46th ECOSOC session.

As regards Resolution of 21.07.2004 no. 2004/40 of the United Nations Economic and Social Council (ECOSOC) "Guidelines for psychosocially assisted pharmacological treatment of persons dependent on opioids", it is addressed, in its operative part, to the World Health Organization (WHO) and does not impose any political obligations on the Member States.

According to Article 21 of the WHO Constitution, the Health Assembly shall have authority to adopt regulations concerning: sanitary and quarantine requirements and other procedures designed to prevent the international spread of disease; nomenclatures with respect to diseases, causes of death and public health practices; standards with respect to diagnostic procedures for international use; standards with respect to the safety, purity and potency of biological, pharmaceutical and similar products moving in international commerce; advertising and labelling of biological, pharmaceutical and similar products moving in international commerce. At that, according to Article 22 of the Constitution, regulations adopted pursuant to Article 21 shall come into force for all Members after due notice has been given of their adoption by the Health Assembly except for such Members as may notify the Director-General of rejection or reservations within the period stated in the notice.

The WHO Model List of Essential Medicines is drafted at the level of an expert committee and approved by the General Secretary of the WHO. This List is not among the aforementioned regulations and consequently has no legal binding effect, being merely a reference for elaborating national lists of medicines.

The said List is regarded as the recommendations meant for assisting countries in development of their own national lists taking into consideration their priority medical and sanitary requirements. Thus, harmonization of national legislation with the List of the WHO is not obligatory for the Member States.

In the light of the aforementioned the Russian Federation does not bear any international legal obligations for review of its laws in full compliance with the said documents, which have an advisory character.

As regards the risks which introduction of "substitution therapy" programmes may entail in the Russian Federation

The Government of the Russian Federation especially emphasize that **introduction of "substitution therapy" programmes in the Russian Federation may entail the following risks**:

- violation of individuals' right to healthcare and medical aid as well as the right to the highest possibly achievable level of physical and mental health;
- support and increasing of drug use among the population;
- increasing cases of drug addiction caused by taking opioids;
- increasing drug-related mortality;
- increasing cases of infection with dangerous accompanying infectious diseases;
- increasing illicit circulation of methadone and buprenorphine;
- degradation of the system of medical narcological aid to the population;
- growth of crime related to involving methadone and buprenorphine users and medical personnel in illicit circulation in methadone and buprenorphine;
- increasing corruption level in the healthcare system and law enforcement authorities;
- destroying the country's demographic, intellectual and creative potential;
- forming of tolerance towards taking narcotic drugs in the society;
- accumulation of a large number of persons dependent on methadone and buprenorphine which can be easily involved in extremist activities and terrorism aimed against the state in general, state agents and particular individuals;
- destabilization of the situation with narcotic drugs in the Russian Federation, with a threat to public safety;
- discrediting of anti-drug policy implemented in the Russian Federation as well as discrediting the activities of the federal authorities of the Russian Federation and the authorities of the constituent entities of the Russian Federation suppressing illicit drug trafficking.

Consequently, the refusal to the applicants to use the "substitution therapy" involving methadone and buprenorphine was fully compliant with the lawful objectives provided for by Article 8 § 2 of the Convention: ensuring national security and public safety, economic well-being of the country, prevention of disorder and crime, protection of health and morals and protection of the rights and freedoms of other persons.

On mortality as the result of taking drugs among participants of "substitution therapy" programmes in Europe[6]

Beginning from mid-1960s "substitution therapy" programmes were developed in the countries of the European Communities and Norway. The essence of these programmes is limited to switching users of opiates diagnosed with drug addiction to taking legally received methadone or buprenorphine. In the period from 1993 to 2005 the number of participants of "substitution therapy" programmes in 15 countries - "old" EC Members - grew from approximately 100,000 persons to approximately 600,000 persons.[7]

The biggest growth in number of clients of "substitution therapy" programmes during this period was registered in France (from 3,000 to 17,000), Portugal (from 1,000 to 11,000), Austria (from 2,000 to 7,000). Persons addicted to opiates are to the largest extent included in these programmes in Italy (50%), Great Britain (48%), Germany (42%) and Norway (40%). If calculated as per 100,000 of adult population, the largest number of "substitution therapy" programmes participants was registered in Great Britain (400 persons) and Liechtenstein (350). Methadone expenses in Europe from 1992 to 2005 grew from 700 to 6,000 kgs. "Substitution therapy" programmes use methadone in 79% cases, buprenorphine in 20% cases and other medicines in 1% cases.[8]

Due to acuteness of the problem of high mortality among the participants of the "substitution therapy" programmes its discussion has already come to the pan-European level. Thus, at the annual meeting of experts from EC Member States on the issue of forming the key indicator - Drug-related deaths and scale of mortality among drug users – in the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), held on 29-30 November 2007 in Lisbon (Portugal) the results of research into deaths of participants of "substitution therapy" as the results of overdoses due to wrongly prescribed doses, mixing of the prescribed narcotic drugs with other drugs/substances, weak control over the

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[6] G.V. Pechenkikh, D.N. Chernyshov. On mortality as the result of taking drugs among participants of substitution therapy programmes in Europe (Review based on the materials of the annual meeting of experts from EC member states on the issue of forming the key indicator - Drug-related deaths and scale of mortality among drug users - in the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), held on 29-30 November 2007 in Lisbon, Portugal).

[7] The data are provided based on the presentation of EMCDDA official Dagmar Heddrich «Review of the existing data on substitution therapy in Europe».

[8] The data are provided based on the presentation of a French representative - Dr William Lowenstein from the Rotschild Institute for drug addiction treatment research "Buprenorphine in France: from 0 to 95,000 patients during 10 years".

programme's progress on the part of medical workers, suicides, etc. were presented in 9 of 19 speeches.

In the EMCDDA annual report on the state of the drugs problem in Europe for 2007[9] it is noted that high level of mortality among the participants of "substitution therapy" programmes carried out under control of doctors raises concerns.

EMCDDA experts, along with a number of other European researchers, acknowledge **that the total number of "drug addicted persons" did not change following their inclusion in "substitution therapy" programmes - they "moved" from the group of users of heroin and other opiates to the group of users of methadone or buprenorphine.**[10]

Below reference is provided to the opinions of foreign specialists on the problems which arise in the course of practical application of substitution therapy programmes, including those on the issue of mortality of participants of "substitution therapy" programmes in the course of and resulting from the "treatment" and the causes of these deaths.

On 13.08.2006 *Sunday Gazette* newspaper (USA) published an article «**Lethal outcomes resulting from methadone tripled every four years. The number of prescription was still increasing notwithstanding instances of overdose resulting in deaths.** It provided the following data: «The Disease Control Centre informed that **the number of Americans who died from overdoses of methadone - the narcotic drug given by medical prescription, increased by 213% during the four years between 1999 and 2002**». «Methadone accounted for more than one-third of deaths from opiate narcotic drugs. The increasing number of deaths from methadone was accompanied by its increasing prescription as a painkiller in hospitals which did not deal with drug abuse treatment». «This continued to discredit the drug, as well as its use for treatment of diseases».[11]

Statistical data regarding similar developments in other States may be provided:

In Lithuania, the methadone programme started in 1996 as alternative treatment for heroin addicts, on the initiative of the public movement "Drug addicts and their parents in support of methadone", and just **within the first two**

[9] Annual Report on the state of the drugs problem in Europe for 2007, prepared by the European Monitoring Centre for Drugs and Drug Addiction.

[10] See: T.B. Dmitriyeva, N.N. Ivanets, V.N. Krasnov, A.S. Kononets, A.S. Tiganov. No to Methadone Programmes in Russia! (They can not be regarded as a platform for medical treatment) // Meditsinskaya Gazeta (Medical Newspaper). 2005. 30 March; Narkokontrol (Drug Control). 2006. No. 2. P. 43-48.

[11] The data are provided based on the speech of Axel Heinemann, representative of the Hamburg University in Germany «Overdosing of methadone and buprenorphine: toxicological aspects».

weeks of its application two drug addicted persons died of overdose of methadone. This tragic incident demonstrated once again what was the outcome of methadone programmes implementation. At the UN INCB 66th Session in May 1999, during discussion of the Swiss "experiment" for distribution of narcotic drugs among drug addicts the German INCB member O. Schroeder said that **in the preceding years serious complications had been registered more frequently after taking methadone, and mortality had increased almost twice.** The newspaper *Frankfurter Allgemeine Zeitung* in the issue of 04.05.1999 proposed to use methadone in a more careful way and strengthen control over its use, as **in 1997 100 drug addicted persons died in Germany as the result of using methadone, and as many as 240 such persons died in 1998.**[12]

Axel Heinemann, the scientist from the Hamburg University, provides the data that **in Germany 150 persons died in 2002 due to the reasons related solely to "substitution therapy". In 2003-2006 this mortality rate remained at the level of 50-70 persons.** Due to reasons, related to "substitution therapy" when it was one of the factors, the number of death incidents in Germany reduced from 450 in 2002 to 130 in 2006. The ratio of the number of overdose incidents due solely to "substitution therapy" reasons to the total overdose incidents related to "substitution therapy" in 2002 amounted to 32%, in 2003-2004 this ratio decreased and amounted to 15%, and later in 2006 it increased reaching 40%. **Of 903 overdose incidents registered in Germany in 2006, 60 incidents occurred in the course of "substitution therapy" programmes, 152 incidents were related to "substitution therapy" programmes. Of these 903 overdose incidents, 60 relate to purely methadone overdoses, 132 incidents were related to methadone and other substances, 2 incidents were related to buprenorphine.**

In Great Britain, in 2005 in 199 incidents of deaths from methadone 66 persons were using the drug based on doctors' prescription. In England every 33rd participant of treatment programme using methadone dies. In 27 incidents of deaths from buprenorphine in Great Britain, 8 persons used it based on doctors' prescription.[13]

[12] See: V.N. Krasnov, N.N. Ivanets, T.B. Dmitriyeva, A.S. Kononets, A.S. Tiganov. No to Methadone Programmes in Russia! (They can not be regarded as a platform for medical treatment) // Meditsinskaya Gazeta (Medical Newspaper). 2005. 30 March; Narkokontrol (Drug Control). 2006. No. 2.

[13] The data are provided based on the speech of a representative from Great Britain John Corkery from the International Centre for Drug Policy (ICDP) at St George's, University of London «Mortality and substitution therapy in Great Britain».

In Finland, in 2000-2006 heroin-related mortality decreased from 60 cases per year to practically zero, while at the same time **buprenorphine-related mortality increased from practically zero values to 85-90 deaths per year.**[14]

In Denmark, growth of methadone-related mortality is also related to development of "substitution therapy" programmes. There is continuous growth of the number of clients of "substitution therapy" programmes from 120 (in 1990) to more than 300 (in 2006). **At the same time in 1991 there were registered 50 deaths of clients of "substitution therapy" programmes, in 1997 - 40, and from 2002 to 2006 this mortality rate remained at the level of 60-80 incidents per year.**[15]

Thus, in 2005 **in Denmark methadone was the cause of 43% drug-related deaths, in Germany - 17%, in Great Britain - 14%. In Spain in 2005, 2% of the total number of persons who died from drugs died solely because of methadone poisoning. At that, methadone was found with 42% of persons who died because of using opiates and with 20% of persons whose deaths were caused by cocaine. High level of buprenorphine-caused mortality is registered in France and Finland. Deaths caused by buprenorphine were registered in Great Britain.**

This situation is observed not only in Europe. Thus, **in Australia of 843 registered deaths occurred as the result of overdose 78 incidents, i.e. 9%, are methadone-related. 67% of the persons who died as the result of methadone overdose are participants of "substitution therapy" programmes.**[16]

Demonstration of statistical data on mortality resulting from overdose, including deaths of participants of "substitution therapy" programmes may be continued in respect of other European States as well. However, the data which have already been mentioned demonstrate with sufficient degree of clarity that the European States faced a number of problems when developing "substitution therapy" programmes. Among the main problems of this kind is a great number of deaths of participants of "substitution therapy" programmes. Notably, a significant number of these mortal incidents is directly connected with

[14] The data are provided based on the speech of a delegate from Finland, Dr Jouni Tourunen, "Buprenorphine in Finland. 10 years after beginning of use of substitution therapy".

[15] The data are given based on the speech of a representative of Denmark Henrik Beylau from the National Health Council of Greater Copenhagen District «The situation with use of methadone in Denmark».

[16] The data are provided based on the speech of a representative of Australia Professor Shane Darke from the National Drug & Alcohol Research Centre of New South Wales University in Australia «Methadone-related deaths: toxicology and systematicity of the diseases».

participation in "substitution therapy" programmes or was a direct consequence of this "treatment".

One of the main reasons of the high mortality level among participants of "substitution therapy" programmes named by foreign experts in the first turn are the factors related to the peculiarities of pharmacology and pharmacokinetics of the substances used in such programmes.

For example, the representative of Germany Axel Heinemann (Hamburg University), examining the pharmacological profile of methadone notes that its peak effect on the brain comes 1-2 hours after intravenous administration and 6-8 hours after oral administration. The average half-life of methadone in the organism is 26.8 hours. Its full excretion may occur within the range from 13 to 55, or even to 72 hours. For buprenorphine the period of its full excretion from the organism is approximately 37 hours. Based on this fact A. Heinemann concludes that inexperienced users of methadone and buprenorphine do not take it into consideration and may allow an overdose.

Examining pharmacodynamics of methadone A. Heinemann notes that its **mixing with benzodiazepines, barbiturates and alcohol increases the possibility of lethal outcome, mainly due to respiratory and cardiac distortion. Negative consequences for health are registered during interaction of methadone with other medicines and narcotic drugs.** The German scientist pays special attention to benzodiazepines which cause a synergistic effect in combination with methadone. **When methadone interacts with other depressants for the central nervous system, like opiates or alcohol, the risk of overdose and death increases considerably. Disinhibition caused by benzodiazepines in combination with methadone may facilitate realization of suicide ideas. The Australian scientist Sh. Darke informs that in his country 5% of all methadone-caused deaths have been recognized suicides.**

According to A. Heinemann, **parallel taking buprenorphine and other drugs may also cause an unpredictable effect.** He notes that **during taking of buprenorphine tolerance to respiratory depression is quickly developed, and this may also be a cause of overdose with lethal outcome.** For example, according to J. Corkery, **43 people died from buprenorphine in Great Britain in 1980-2002.** In 7 cases only buprenorphine was found, in the other cases it was in combination with other opiates.

A. Heinemann also notes that respiratory depression and death can be caused by taking buprenorphine, alcohol and benzodiazepines together with methadone. He notes a number of substances which was most frequently found in Germany (in 1996-2005) together with methadone in cases of overdose: diazepam (in 44.1% of the cases), benzodiazepines (23.7%), doxepin (12.3%), cocaine (12.7%), morphine (5.9% of the cases). For the overdose incidents registered in Hamburg where more detailed research is carried out, he notes that

in 1992-1999 in the category of persons who died as the result of overdose in whose organisms methadone was discovered (though it was not the main cause of their deaths) approximately 35% were participants of "substitution therapy" programmes. **In those cases when deaths from overdose were caused by methadone, participants (or former participants) of "substitution therapy" programmes constitute about 30%.**

To confirm wide prevalence of these tendencies, one can cite the statement of Professor Sh. Darke who points out that in Australia, during toxicological examination of the blood of the persons who died of methadone overdose there were found other narcotic drugs as well: in 61% of the cases - benzodiazepines, in 35% - morphine, in 21% - alcohol, in 17% of the cases - antidepressants. Comparing the toxicological tests carried out in case of deaths caused by methadone or heroin he notes that benzodiazepines in combination with methadone were found in 61% of the incidents and in combination with heroin - in 25% of the incidents, combination of alcohol with methadone - in 21% of the incidents and with heroin - in 42% of the incidents, combination of antidepressants with methadone - in 17% of the incidents and with heroin - in 10% of the incidents.

In Denmark, 19 of 20 persons, who died from methadone, had traces of opiates taken together with methadone. Notably, in 9 death incidents of 10 methadone was used on a constant basis but not for detoxication at the initial treatment stage.[17] In Spain, as noted by T. Brugal, the main cause of the lethal incidents from methadone overdose is abuse of heroin or cocaine by participants of substitution therapy programmes.[18]

The provided data on deaths which occurred as the result of mixing by participants of "substitution therapy" programmes of methadone or buprenorphine, prescribed by medical workers, with other substances **demonstrate that methadone (buprenorphine) is regarded by them not as a medicine but rather as another narcotic drug though with a lower intoxicating effect. This refutes the argument of some Western specialists that methadone therapy allows to decrease the dose of taken narcotic drug up to complete refusal from taking the drug.** This also **breaks the other argument** of "substitution therapy" supporters - that motives for further

[17] The data are given based on the speech of a representative of Denmark Henrik Sejrha from the National Health Council of Greater Copenhagen District "The situation with use of methadone in Denmark».

[18] The data are provided based on the speech of a representative of Spain - Dr. Teresa Brugal from Barcelona Healthcare Agency "Substitution therapy, what causes mortality? (Barcelona case study)".

treatment can be created for drug addicts if they develop contacts with experts who professionally deal with drug addiction treatment.[19]

Alongside with poly-drug use Western experts point out to such factor as methadone tolerance which influences the growth of death incidents among "substitution therapy" programmes participants. Thus, according to A. Heinemann, daily methadone dose may vary from 5 to 1,200 mg per day. The process of forming of methadone tolerance with some people may last up to 12 months. However, cross-tolerance does not exist, meaning that if a person is tolerant to heroin it does not guarantee that this person will be tolerant to methadone as well. It is easier to overcome methadone tolerance threshold than heroin tolerance threshold. As **eventually during use of methadone the difference between the dose causing intoxicating effect and the dose causing respiratory depression lessens, the risk of overdose for experienced users is increased.**

This feature of methadone poses, with greater urgency, before the organizers of substitution therapy programmes the questions of choice of the type of administration and dosage of the used substances and taking care of control over use of such substances. **Western experts believe that impossibility of accurate dosage of methadone or buprenorphine, lack of relevant knowledge and weak control over the process of their dosage and use also contribute to growth of death incidents among participants of these programmes.**

For example, speaking about the factors leading to overdose during taking narcotic drugs within the framework of "substitution therapy" programmes, A. Heinemann notes that normally (in Germany) buprenorphine is manufactured in form of pills, making difficult visual determination of dose. Taking of a pill sublingually (under the tongue) during 5-7 minutes renders difficult control of the process of medication and its correctness.

J. Strang from National Addiction Centre in Great Britain also believes that accidental overdose may only be avoided by oral taking of narcotic drugs in form of syrup. Thus, with regard to methadone he states that its taking in form of sublingual pills complicates control over its dose and increases the risk of accidental overdose. In Great Britain, in 1995 of the total number of people who were prescribed methadone, 79.6% obtained it in the form suitable for oral administration, 11% - in form of pills and 9.3% - in ampoules. In 2005, 96.4% of such persons obtained it in form of mixture, 1.75% - in form of pills, 1.85% - in ampoules.

At the same time, Professor Sh. Darke notes the existence of problems with administration of methadone in form of injections (when methadone is

[19] This opinion is shared by Dr. M. Kooyman from the Rotterdam University, the Netherlands (cited as per the article of V.N. Krasnov, N.N. Ivanets et al. in the Meditsinskaya Gazeta of 30 March 2005).

supplied in liquid form), and Dr. J. Tourunen points out that in Finnish medical practice buprenorphine pills are mainly used, and, in her opinion, such pills are easy to split to choose the dose. W. Lowenstein also notes that in France buprenorphine was prescribed only in form of sublingual pills. In his opinion, such form of taking ensures impossibility of overdose. In substantiation of his assertions he notes that in France 95,000 patients have already undergone buprenorphine substitution therapy. However he operated the data on the total number of lethal incidents resulting from overdose, without singling out the number of substitution therapy programmes participants in this total number. According to him, in France such type of statistics is not kept officially.

At the same time, Dr J. Tourunen points out to the fact that the situation in illegal trafficking in Finland is quite different from the situation in the medical practice. Of the total number of persons taking buprenorphine for non-medical purposes 83% use it in form of injections, 9% use sublingual pills and 8% inhale it through the nose. Possibly, it may be indirect evidence of the fact that taking narcotic drugs in form of liquids allows to more precisely control their dose.

Experts have no common opinion either so far as dosage of methadone and buprenorphine prescribed for medical purposes is concerned.

Speaking about methadone, Professor Sh. Darke notes that in Australia the initial prescribed daily dose varies from 20 to 40 mg per day, while the therapeutic recommended daily dose is equal to 80 mg per day. In Spain, average daily methadone dose is 71 mg per day.[20] In Great Britain, the recommended therapeutic range for methadone is 60-120 mg per day. However, in 1995 the daily dose amounted to 47.3 mg per day and in 2005 - 56.3 mg per day. The doctors made 27.5% of all methadone prescriptions within the limits of the recommended therapeutic range in 1995, in 2005 - 40.1% of all prescriptions.[21]

Speaking about buprenorphine, J. Strang informs that in 2005 in Great Britain doctors made 53% of all prescriptions within the recommended therapeutic range (8-16 mg per day). **This may be regarded as evident sign of the concerns experienced by practising doctors when prescribing methadone, even with recommendations of the relevant medical authorities.**

His compatriot J. Corkery notes that **buprenorphine causes significantly less deaths than methadone, however in the recent years, with spreading of**

[20] The data are provided based on the speech of a representative of Spain - Dr. Teresa Brugal from Barcelona Healthcare Agency "Substitution therapy, what causes mortality? (Barcelona case study)".

[21] The data are provided based on the speech of a representative of Great Britain - Professor John Strang from the National Addiction Centre «Does prescribing for opiate addiction change after national guidelines? Methadone and buprenorphine prescribing to opiate addicts by general practitioners and hospital doctors in England, 1995-2005».

the practice of prescribing larger doses of buprenorphine within "substitution therapy" programmes the number of death incidents is growing drastically. In 2004-2005 the average daily buprenorphine dose amounted to 8.9 mg per day which is significantly less than the upper limit of the therapeutic recommended dose of 16 mg per day. It is believed that there will be no abstinence if the buprenorphine dose amounts to 12-24 mg per day. **After licensing of buprenorphine in Great Britain in 1999 the prescribed doses increased drastically (3-fold). In the same period the number of buprenorphine-caused deaths also increased 3-fold.**

W. Lowenstein also points out to **existence in France of a number of measures for limiting the prescribed doses; such measures are intended to prevent accidental deaths among substitution therapy programmes participants (or to reduce the number of such deaths).** For example, the initial daily methadone dose is established within the range of 10-40 mg per day, buprenorphine - 4-8 mg per day. Dose increase scale is regulated as follows: for methadone - by 5-10 mg per day for 1-3 days, for buprenorphine - by 1-2 mg per day during 1-3 days. In Finland increasing the doses for buprenorphine users for medical treatment purposes at home is effected not more often than once in 8-14 days.

The most vivid evidence of failure of methadone programmes is the information which has appeared from the Australian Government as regards switching to "heroin ration" for drug addicts, to replace methadone. The Australian Embassy in the Russian Federation in its letter of 15.08.1995 no. 18, justifying its Government's position, noted, in particular: **"The practice of giving methadone decreases its effectiveness. Because methadone does not give the sought-after euphoric high, drug addicts give it up."**[22]

In order to prevent incidents of death among "substitution therapy" programmes participants when they make use of methadone and buprenorphine the persons in charge of these programmes apply a number of other measures of organisational character. Thus, in Australia it is not allowed to transfer patients to taking methadone at home within the first three months of their participation in "substitution therapy" programmes. If such decision is taken the person must demonstrate a totality of good clinical parameters (positive tests results, stable tolerance to the drug, etc.). The prescribed dose must comply to the dose issued by the pharmaceutical industry (in order to exclude the possibility of mistake during independent dosage). In Spain the patients of "substitution therapy" programmes are obliged from time to

[22] Cited as per: V.N. Krasnov, N.N. Ivanets, T.B. Dmitriyeva, A.S. Kosorots, A.S. Tiganov. No to Methadone Programmes in Russia! (They can not be regarded as a platform for medical treatment) // Meditsinskaya Gazeta (Medical Newspaper). 2001. 30 March; Narkokontrol (Drug Control). 2006. No. 3.

time to undergo medical tests, psychophysiological examination and to participate in training programmes. In Finland and Austria buprenorphine is supplied for persons taking it at home for medical treatment purposes in combination with naloxone (with exception of pregnant women). In Great Britain daily distribution and controlled taking of methadone are used in general, not allowing to create reserves of methadone. Only licensed methadone treatment is allowed, and distribution of narcotic drugs in Great Britain is organized through a pharmaceutical society.

Nevertheless, mortality among methadone and buprenorphine users, who are mostly participants of "substitution therapy" programmes, still remains high. In order to understand the reasons thereof, A. Heinemann made a classification of death incidents caused by methadone:

1. He singled out three groups in the category of narcotic drugs users who receive medical aid:

1.1. Those to whom methadone was administered on therapeutic level. Death occurred:

- in the first days of treatment due to therapeutic overdose;
- as a result of abuse of office by medical personnel;
- due to accident related to simultaneous use of other medicines or narcotic drugs (mostly heroin).

1.2. Those to whom methadone was administered on levels less than the therapeutic level. Death occurred:

- due to accident related to simultaneous taking of other medicines or narcotic drugs (mostly heroin);
- due to inner reasons which have not been established.

1.3. Those who used methadone on poisonous or lethal level. In this group death occurred due to accidental or wilful poisoning.

2. Apart from the previous category he considers the category of methadone users who do not receive medical aid and are not controlled, that is, use methadone which is in illegal circulation.

Taking the reason of death as the basis for the classification A. Heinemann divided the death incidents related to methadone in the following three categories:

- methadone was used for good purposes and was not the cause of death;
- methadone is the main or one of the important causes of death;
- methadone is the only cause of death.

The third type of classification proposed by A. Heinemann is based on the study of the typical circumstances causing methadone overdose, which was conducted by him:

1. News of sudden disaster.
2. Lack of knowledge - with intravenous administration.
3. Overdoses occur mostly in the evening rest hours.

4. Overdoses often occur when the drug is taken in the presence of other people.

5. Poor coordination of the person's actions with "substitution therapy" course or self-treatment.

6. Missing the daily dose and it subsequent taking together with the next dose.

Many specialists confirm the reasonableness of this classification.

For example, the third classification type proposed by A. Heinemann, is compliant with the data which Sh. Darke provides for Australia. 73% death incidents took place at home. 89% of the dead persons were unemployed. 6% are persons recently released from convictions (all of them were males). The conducted serological studies of tissues have shown that 8% of the dead persons had HEV (all of them were males). Hepatitis was found with 82% of the dead men and with 69% of the dead women. 5% of all deaths from methadone occur as the result of suicide.

In Australia, toxicological analysis of concentrations of methadone in the dead persons' blood showed that a clearly expressed maximum is found with its relatively small concentration - 0.21-0.4 mg/l. With larger concentrations the number of discovered death incidents is much less. **This may point to those persons to whom methadone was administered on therapeutic level and whose deaths occurred in the first days of the treatment due to wrongly calculated dose.**

EMCDDA experts note that the classifications proposed by A. Heinemann allow better understanding of the shortcomings in organization of "substitution therapy" programmes. However, better meaning of these classifications is seen in the possibility of their use during organization of general prevention work for prevention of overdose-related mortality among drug users, determining risk group among such users as the priority audience for such work.

In the Western countries, a disappointingly high mortality level among "substitution therapy" programmes participants and their structure as per groups (according to A. Heinemann's classifications) **have brought up the issue of insufficient qualification of medical personnel who organize this work, and shortcomings in organization of the work of the relevant medical institutions.**

A. Heinemann notes poor knowledge of some particular features of clinical use of methadone by German therapists.

J. Strang notes that in Great Britain the problem of poor qualification of medical workers who deal with "substitution therapy" programmes also exists. To solve this problem, the National Institute for Health and Care Excellence has developed and issued a number of guidelines.

In France the guidelines for conducting "substitution therapy" were developed by the "compromissory conference" which was held in Lyon in June 2004. At the same time, W. Lowenstein draws attention to the fact that not the

existence of the guidelines but rather their understanding by practising therapists and application in medical practice are more important. According to him, there were incidents when therapists prescribed buprenorphine for persons addicted to hashish or prescribed very large doses. **Some problems were not solved at the "compreminary conference", among them: incorrect use of methadone and buprenorphine which may lead to overdose; existence of the "black market" of substitution therapy services; growth of accompanying use of alcohol, benzodiazepines, cocaine and other substances.**

Therefore, for implementation of "substitution therapy" programmes their organisers and participating medical personnel need knowledge on quite a high level. The aforementioned data clearly demonstrate that the level of knowledge of medical workers in the Western countries is evidently still insufficient to ensure carrying out "substitution therapy" programmes in such a way which would be safe for the programmes' clients.

Another problem related to the level of training of the relevant medical workers is caused by the fact that even in the absence of a lethal outcome serious health problems may occur as the result of methadone overdose. Thus, Professor Sh. Darke points to various diseases of liver, cardiovascular system, lungs as well as various combinations of these diseases. According to him, **liver problems emerge in 80% of methadone overdose incidents** and only in 63% incidents of heroin overdose, **cardiovascular system diseases emerge in 39% methadone overdose incidents** and only in 29% heroin overdose incidents, **lung diseases - in 49% methadone overdose incidents** and only in 23% heroin overdose incidents.

Even in the absence of overdose there are scientific facts regarding the grave consequences of taking methadone. Thus, while heroin withdrawal syndrome lasts on average 5-7 days, methadone withdrawal syndrome lasts up to 40 days.[29] Methadone addiction has the following

[29] E.A. Babayan in his article "Use of methadone can not be regarded as treatment" (Novaya Apteka. 2003. No. 3. P. 19-22) stated: "Interesting observations were made by Professor A.G. Gofman who works in one of the Moscow clinics with patients who are methadone addicts... Usually methadone is taken by patients suffering from heroin addiction or processed opium abuse. **The initial aim of taking methadone consists in facilitating the person's condition after termination of taking the drug. However, in the overwhelming majority of cases the patients are not able to limit themselves to taking methadone one or two times. There happens replacement of the drug: instead of taking heroin (processed opium) they start taking large doses of methadone on a daily basis. According to the patients, the feeling of euphoria caused by methadone ("methadone rush") is in no way worse than the euphoria caused by heroin. The first manifestations of the withdrawal syndrome begin on the 2th-4th day after the last taking of the drug. Such withdrawal syndrome lasts much longer than with heroin addiction and other drug**

specific features: frequent increase of weight not observed in case of heroin addiction, development of oedemas on arms and legs, cardiomyopathy, hepatitis, liver cirrhosis, lung dysfunction, development of suffocating feeling, sleep disorder, nightmares.

Moreover, it needs to be emphasized that wide development of "substitution therapy" programmes provokes leakage of methadone or buprenorphine into illicit trafficking and causes the problems which are quite typical for such situation (criminal growth, corruption among medical workers, etc.).

Alongside with that, it should be noted that, **taking into consideration the specific pharmacological features of these narcotic substances increasing their share in illegal trafficking exerts significant influence on increasing mortality level among drug addicts who do not participate in "substitution therapy" programmes.** This problem is especially urgent due to the fact that taking methadone and buprenorphine in this case is effected not under medical workers' supervision. In this situation the possibility of overdose increases significantly.

W. Lowenstein notes **the connection between growth of the amount of prescribed methadone** (every year about 2,000 new patients are added in France) **and growth of its amount in the "black market", increasing number of persons who use it for non-medical purposes.** Similar interdependence existing in Great Britain is noted by J. Corkery. **The number of forensic medical examinations in the course of which buprenorphine was discovered in dead persons who have died as the result of overdose in Great Britain increased from 43 in 2000 to 421 in 2007.**

The interconnection between development of "substitution therapy" programmes and growth of illicit methadone and buprenorphine trafficking is noted by Dr. J. Tourunen, too. Implementation of "substitution therapy" in Finland began in 1997. In 2007 there were 8,000 - 10,000 persons addicted to opiates in Finland, and 70-80% of these persons used buprenorphine for substitution therapy. **The status of a therapeutic substance and low cost accounted for its leakage into illicit trafficking.** She notes that **as the result of the same buprenorphine has become very popular in the "black market" and this has even provoked development of "drug tourism" to Finland connected with this drug. As the result, there was registered the growing number of death incidents related to buprenorphine: in 2006 their number reached 88.** According to her, **in 2007 there were at least twice as much intoxications in Finland related to buprenorphine than those related to heroin.**

addictions and is difficult to cope with. Notwithstanding active treatment, somatic vegetative dysfunctions normally disappear after two weeks".

In Spain, where "substitution therapy" programmes use mostly methadone, after wide spread of these programmes, **the specific share of narcotic drugs discovered in drug-related death incidents has changed as follows. From 1995 to 2006** the share of opiates decreased from 90 to 70%, the share of cocaine increased from 10 to 70%, discovery of benzodiazepines decreased from 50 to 40%, while at the same time **the share of methadone discovered in drug-related death incidents increased from 15 to 40%.**

The formed situation induced T. Brugal to carry out a research into the fact concerning the influence of methadone programmes on mortality from overdoses and spreading of AIDS in heroin addicts groups. As the result, **it was established that after including heroin users in "substitution therapy" programmes their mortality structure has changed in the following manner.** AIDS-related deaths number has decreased from 38 to 26%. But **the share of overdose-related death incidents has increased from 35 to 39%**. Mortality caused by other reasons has increased from 27 to 35%.

Denmark demonstrates similar tendencies. From 1991 to 2006 mortality caused by heroin (morphine) decreased from 61 to 38% of all drug-related death incidents. **Methadone-related mortality in this period increased from 33 to 42% of all incidents.** The share of other drugs in death incidents also increased from 10 to 20%. **H. Seylan states that stable mortality growth may be spoken about only in relation to methadone.**

All the aforementioned researchers point out to the fact that, similar to the incidents of death of the programmes' participants outside the "treatment" course, **death incidents among methadone and buprenorphine users who obtain the drugs in the "black market" are largely caused by their combination with other narcotic drugs. This allows to put to doubt another argument of "substitution therapy" programmes supporters - that these programmes allow to decrease mortality level among drug addicts on the whole.**

In order to organise the measures of preventive and other influence on this risk group taking methadone or buprenorphine it would be practicable to study this group's particular features. The social portrait of this group can be partly drawn by carrying out a sociological study of "substitution therapy" programmes participants. This issue is already being solved by Western specialists.

Thus, resting upon the issue of non-medical use of buprenorphine in Finland, J. Tourunen notes the following characteristics of drug users which have been discovered during a survey in 2006. In the age group of 24-34 years of age up to 1% of persons were taking buprenorphine within the preceding month. 31% of all buprenorphine users used it as the first narcotic drug with which their drug abuse has begun, and 15% have tasted it only once. Of the questioned buprenorphine users, 34% responded that they were using it daily, 59% of those questioned had been using it within the preceding month and 78% responded that they were using it rarely - from time to time. Of all drug users in

Finland, 73% responded that they were using buprenorphine with an average single dose of 7 mg per day. **72% of buprenorphine users are poly-drug addicts.**

In addition, J. Tourunen notes that among those who use buprenorphine for non-medical purposes as well as within the framework of "substitution therapy" programmes 65-70% are men aged 28-30, 60-76% are single, from 45 to 73% have graduated from only secondary school, 62-85% are unemployed, 6-12% are homeless, 41-65% have various mental disorders, 55-85% are infected with hepatitis C.

In Denmark, the number of persons who died from methadone at the age of 35-44 is at least twice more than in other age groups (15-24 or 25-34). The majority of the dead persons had only school education, that **allows H. Seylan to explain such high mortality level among "substitution therapy" programmes participants by the lack of knowledge at their initial stage of involvement in the programme. In addition, in 1997 there were changes in the Danish healthcare system, and daily methadone doses increased: prescriptions of 125 mg/day became generally accepted practice.**

This confirms once again the above-mentioned enumeration of the key factors which account for high mortality level among the clients of "substitution therapy" programmes.

These are, primarily, the pharmacological characteristics of methadone (buprenorphine) which require more exact dosing of these drugs, taking into consideration their interaction with other medicines and narcotic drugs.

The length of the period of methadone excretion from the organism requires planning of its use and control of clinical parameters on the part of medical workers.

All these factors imply the existence of good professional training of medical workers and sufficiently high education level of the clients of "substitution therapy" programmes.

For the time being, as demonstrated by foreign states' practice, participants of "substitution therapy" programmes are mostly in another social stratum. The socialisation problems of drug users cause failures in planned and controlled development of the programmes recommended to them and cause the risk of accidental overdoses or mixing the prescribed substances with other substances entailing a lethal outcome.

Overdosing of the substances used in "substitution therapy" programmes, without a lethal outcome, and even their mere use inflict significant damage to the patients' health and increase the risk of negative consequences, even without overdosing.

Therefore, **the experience of realisation of "substitution therapy" programmes** using methadone and buprenorphine, which has been acquired in foreign countries **allows to conclude that development of these programmes does not lead to decreasing of overdose-related mortality level. On the**

contrary, the risk of accidental overdose of methadone or buprenorphine is higher as compared, for example, to heroin. The risk of lethal outcome during taking methadone or buprenorphine is high even in the conditions when they are taken under medical workers' supervision.

The argument about positive influence of "substitution therapy" programmes on decreasing of mortality level among drug addicts on the whole does not stand up to criticism either. On the contrary, **existence of large amounts of legally distributed methadone or buprenorphine inevitably leads to their leakage into illicit circulation and growth of the scale of their use for non-medical purposes.** Being more accessible, **they oust heroin from the "black market" and increase the level of mortality among opiates addicts caused by overdosing.**

This conclusion evidently follows from the fact that, on the one part, "substitution therapy" programmes are widely spread in Europe, and on the other part - according to EMCDDA annual report for 2007 - **drug-induced mortality in Europe still remains high. Mortality resulting from overdose remains at the level of 7,000 - 8,000 dead persons per year.** Europe still shows no tendency for decreasing of drug-caused mortality level. **In 2004-2005 4% of all death incidents among Europeans aged 15-39 were connected with drugs, and in nine European countries this rate was more than 7%. From 2002 to 2005 considerable growth of drug-related mortality was registered in Austria, Greece, Portugal and Finland.**

Based on the aforementioned data, other "positive" consequences of "substitution therapy" programmes argued by Western specialists can be criticized as well. Thus, **leakage of methadone and buprenorphine into illicit circulation causes increase in the level of relevant crime and corruption in the sphere of healthcare.**

"Legalization" of drug addicts through substitution therapy programmes raises the issue of their reproduction through family relations. In EMCDDA annual report for 2007 it is noted that **the teenagers in families where there are drug users face greater risk of beginning using them, notably at earlier age.** In 2007, there were about 28,000 persons in Europe who were undergoing a course of "treatment" for drug addiction and resided together with their children.

The argument of Western specialists **that participation in "substitution therapy" programmes may be considered as an effective measure for reducing the dose of used drug up to termination of its use breaks up if we examine the statistic data showing that other narcotic drugs were found in the blood of the deceased participants of these programmes. A significant number of "substitution therapy" programmes participants return to taking drugs which give bigger euphoric effect.**

In view of the aforementioned we **should conclude that high mortality level among "substitution therapy" programmes participants refutes the**

main statements of the Western specialists regarding their positive influence on the situation concerning drugs and increasing control over the processes going on in this sphere. This is confirmed by the aforementioned data contained in this Memorandum **obtained from the experts who studied the issue in those countries where "substitution therapy" programmes have widely spread and where vast experience of implementation of such programmes has been accumulated.**[34]

"In our opinion, a number of steps may be marked in the methadone programme, which can be regarded as its crisis. The first step in 1961 when methadone was included in Schedule I of the Single Convention on Narcotic Drugs of 1961 along with heroin as equally dangerous drug; the second step when the Commission accepted the position of a number of countries, in particular the Soviet Union, which considered the methadone programme not a medical one but simply replacing one drug by another drug leading to equally disappointing consequences. And lastly, the present stage, when supporters of the methadone programme started speaking openly that the programme has not proved its value and that they are returning to heroin (the experience of Switzerland[35], Australia), may be regarded as the failure of the methadone programme."[36]

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[34] See more details in the following publications:

1. Wolffe R. (2002). Characteristics of methadone overdose: clinical considerations and the scientific evidence. Therapeutic Drug Monitoring 24, 455-470.

2. Corkery J. et al. (2004). The effects of methadone and its role in fatalities. Hum Psychopharmacol Clin Exp. 19, 59-376.

3. Pirnay S. et al. (2004). A critical review of the causes of death among postmortem toxicological investigations: analysis of 34 buprenorphine-associated and 35 methadone-associated deaths. Addiction 99, 919-928.

4. Reduction in the number of lethal overdoses in France since 1996, B. Lapeyre, L. Gosmier, M. Sanchez and Lowenstein; Ann. Med. Int., Supp. to N 3, April 2001.

5. Darke S., Kaye J. & Duflou J. (2006). Systemic disease among cases of fatal opioid toxicity. Addiction, 101, 1299-1305.

6. Darke S., Degenhardt L. & Mattick R. (2007). Mortality amongst illicit drug users: epidemiology, causes and intervention. Cambridge: Cambridge University Press.

7. Bengal M.T., Domingo-Salvany A., Puig R., Barrio G., Garcha de Olalla P., de la Fuente L. Addiction, 2005; 100:961-89.

[35] At the Commission on Narcotic Drugs (CND) session in 1994, a Switzerland representative declared officially that the government of his country was planning a new experiment – give heroin to patients with heroin addiction. Among the reasonings and explanations of this action of the Swiss Government (which invoked sharp criticism and also because the subject of a special discussion at the International Narcotics Control Board), the Swiss representative noted that the Government thought it was necessary to switch to heroin, because methadone use did not produce the expected results. It did not become a great

All the countries which had been implementing (and some of them are still implementing) methadone programmes, along with other grave drug addiction cases, also acquired a new problem of methadone addiction, which is clearly noted in the UN INCB reports and statements. However it is a well-known fact that search of new arguments in support of methadone, which has already compromised itself, is still going on. This is explained by the fact that it is much simpler to give out methadone than to organise protracted treatment for patients.[27] In some countries, the business interests of manufacturers of this narcotic drug, which is quite expensive, prevail over the life and health of drug addicted persons.

Data on some publications in foreign media about the destructive effect of substitution methadone treatment

No.	Media Name	Article
1.	Ukrainian Psychiatry News. Ukraine, 2005 http://www.psychiatry.ua	**On substitution therapy for drug addicts using methadone - among other things.** "...It is not accidental that **mortality among persons receiving substitution methadone therapy is higher than among those persons who have remained beyond methadone maintenance programmes**, as in the former case the effect of a "street" drug overlaps the effect of methadone, thus leading to overdose."
2.	Interfax-Ukraine Agency. Ukraine, 2007. http://gazeta.2000.ua Citizens Commission on Human Rights. Ukraine, 2012. http://mentalhealth.org.ua	Will "cash" dictate its own laws? "Mortality growth. Moreover, those countries where substitution therapy has been widely spread demonstrate a drastic increase in mortality caused by opioids, in the first turn by methadone. A disastrous situation has formed in the USA where methadone-related mortality in the period from 1999 till 2004 increased four-fold amounting to 3,849 persons in 2004, which **exceeds twice the mortality caused by heroin**. For justice sake it should be said that a special commission of the US Government concluded that "the main killer" was not methadone from substitution therapy programmes, but the methadone prescribed as painkiller by general practitioners. However, the commission's findings do not explain why the maximum, eleven-fold (!) mortality increase was registered among young people aged 15-24, as teenagers and young men used painkillers less frequently than old people..."
3.	Вісник психіатрії та психофармакотерапії. (Psychiatry and Psycho-Pharmaco therapy Bulletin) Ukraine, 2008. http://www.psychiatry.ua	**Contribution of injection drug users in spreading of HIV infection and implementation of substitution therapy programmes.** "...The argument as to the harmlessness of methadone proved to be equally inconsistent. In the recent report of the US National Center for Health Statistics it is shown that during 1999-2004 methadone-related mortality in the United States was growing significantly quicker than mortality caused by any other drugs. As the result, **the number of people who died from methadone in 2004 was 4 times more than in 1999. Moreover, the number of persons who died from methadone exceeded two-fold the number of persons who died from heroin.** For justice sake it should be noted that according to the

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surprise as three years before a similar statement had been made by the Mayor of Amsterdam. - Cited as per: E.A. Babayan. Use of methadone can not be regarded as treatment // Novaya Apteka. 2002. No. 3. P. 19-22.

[26] "In this connection, the article of Dr Martien Kooyman M.D., Ph.D. "The Drug Problem in the Netherlands," published by one of the editions of Erasmus University (Rotterdam, the Netherlands), presents interest. As noted by the author of the article there is a wrong commonly held opinion among specialists and officials that methadone programmes in the Netherlands have been successful. In one of the sections of the article headed "The Third Illusion: Wide-Scale Distribution of Methadone will Put the Problem under Control" the author declares: "Without remarkable success, methadone maintenance programs were introduced in 1968. Drug free treatment in therapeutic communities, developed since 1972, was successful after the first experimental years. This success provided the illusion that drug related problems could be solved by treatment; low threshold programs, putting few demands on participants, were established to dispense methadone. The illusion was that addicts can be motivated into further treatment if they are brought into contact with professionals. As the addict population kept growing and their street crimes increased in number, Dutch drug policies changed in 1978, using methadone as a means to decrease criminal activities rather than to treat addicts. This also turned out to be an illusion. Currently, there is strong political pressure to distribute heroin to addicts to diminish the negative side effects of drug abuse". - Cited as per: E.A. Babayan. Use of methadone can not be regarded as treatment // Novaya Apteka. 2002. No. 3. P. 19-22.

[27] Cited as per: E.A. Babayan. Use of methadone can not be regarded as treatment // Novaya Apteka. 2002. No. 3. P. 19-22.

		conclusions of the special commission called for analysis of the situation described above, the overwhelming majority of the deaths was not related to "substitution therapy" programmes. The main reason behind them was the methadone used for pain management by general practitioners. However this document does not explain the fact that the biggest - eleven-fold (!) - methadone-related mortality growth occurred among young people (aged 15-24), who, as is well-known, less frequently, as compared to elderly people, suffer from chronic pains and consequently less frequently are in need of painkilling using opioids. Such **drastic growth of mortality among young people points to large-scale leakage of methadone to the "black market"...."**
4.	News project of the channel "Inter". Ukraine, 2007 г. http://podrobnosti.ua	**Does using methadone in Ukraine threaten the country's safety?** "...According to **Head of the Managing Board of the Parents' Committee for Combating Drug Addiction** Anatoliy Grytsh **methadone is a dangerous drug and the growth of mortality caused by it is the highest among all known drugs..."**
5.	Novaya Gazeta, Kazakhstan Kazakhstan, 2012 http://www.novgaz.com International information agency KazTAG. Kazakhstan, 2009 http://www.kazteg.kz	**A powerful drug is promoted in Kazakhstan as a medicine.** "...According to the organization "European Cities against Drugs" (ECAD) during 9 years of implementation of the methadone programme in Sweden 33% participants of the programme died and 69% continued to commit crimes. In the Position Paper of WHO, UNODC and UNAIDS «Substitution maintenance therapy in the management of opioid dependence and HIV/AIDS prevention» it is noted that mortality among people suffering from opioid dependence, who receive maintenance methadone therapy, amounts to 25-33%, that is similar to the rate among the people not participating in a similar programme..." "...Mortality among people with opioid dependence, who receive maintaining methadone therapy, amounts to 25-30%..."

6.	Information agency Kazakhstan Today. Kazakhstan, 2013. http://www.megapolis.kz	**The Ambassador of the USA in the Republic of Kazakhstan insisted on using the methadone programme in Kazakhstan.** **"...It is quite difficult to regulate methadone dose and so the percentage of deaths caused by this drug is quite high all over the world..."**
7.	The centre of mental treatment and medical psychology Kiev, Ukraine, 2013 http://medbolotnik.ua	"...The methadone programme was used in many countries including the USA, Australia, China, Sweden, Germany, France, the Netherlands. **It has not solved the problem of drug addiction but increased mortality up to 68%..."**
8.	Information agency K-News. Kyrgyzstan, 2011. http://www.knews.kg	**Ernst Abdyshaparov "Methadone is used in Kyrgyzstan unlawfully"** "...Narcologists' ambitious statements claiming that they are fighting AIDS, crime and drug business are simply an outrage, because of **2,652 persons who entered the programme in 2002, only 966 persons remain there in 2010.** And these are the data from the doctors themselves. And when I asked them what had happened to more than one and a half thousand of the programme participants, who have stopped to use methadone, they replied that it was not their duty, and that the participants come and go voluntarily. They are not keeping any statistics. And the following picture forms, that the positive methadone promotion which is carried out by the doctors, **in reality ends by quick worsening of health and high mortality..."**

As regards use of the "substitution therapy" method in different countries of the world

The majority of the countries of the world (3/4 of their total number) including those which have significant in number groups of drug addicted persons does not allow implementation of methadone programmes. These countries include practically all the states of South America (except for Columbia), many Middle East countries (e.g. Saudi Arabia, the United Arab Emirates, etc.) and such Asian countries as Singapore, South Korea and Japan. The countries openly opposed to "substitution therapy" programmes are Russia, Japan, Turkmenistan and Uzbekistan (where the started programmes were wound up two years ago). In Russia, many authoritative scientists, representatives of civil society, public figures spoke firmly against realisation of

"substitution therapy" programmes. Thus, in the opinion of B.P. Tsilinskiy (Management Academy of the Ministry of the Interior of Russia), substitution therapy is the State's surrender in the face of drug addiction problem.[28] Academician E.A. Babayan regarded substitution therapy as disguised legalization of drugs.[29][30]

Among the Member States of the Council of Europe, "substitution therapy" is not used in Andorra, Monaco, Turkey. There are no data on use of "substitution therapy" in Liechtenstein, San-Marino. "Substitution therapy" is not used in the Holy See (Vatican) which is an observer at the Council of Europe.

In the report of the International Narcotics Control Board for 1999 it is stated: «The Board, recognizing that the spread of drug abuse, human immunodeficiency virus (HIV) infection and hepatitis are serious concerns, encourages Governments to provide a wide range of facilities for the treatment of drug abuse, including the medically supervised administration of prescription drugs in line with sound medical practice and the international drug control treaties, instead of establishing drug injection rooms or similar outlets that facilitate drug abuses (p. 177).

Therefore, **the arguments submitted by the applicants as regards recommendation of "substitution therapy" on a global scale are not true and are just a reflection of the position of some particular countries and international organizations.**

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[28] http://www.narkotiki.ru/sis_1520.html

[29] E.A. Babayan. Legalization of narcotic drugs and international law (interdisciplinary approach) // Narcology problems. 1998. No. 2. P. 58-67.

[30] See also the following publications dedicated to this problem:

V.N. Krasnov, N.N. Ivanets, T.B. Dmitrieva, A.E. Kononets, A.S. Tiganov Memorandum "No to methadone programmes in the Russian Federation (use of methadone can not be regarded as medical treatment) // Socially significant diseases in the Russian Federation: Collection ed. by L.A. Bokeriya and I.N. Stupakov. – NTsSSKh named after A.N. Bakulev. – Moscow, 2008. 79-83.

Danger – methadone! (Substitution methadone therapy in "Heroin rehabilitation programmes") / Counseling Orthodox Center of St. John of Kronstadt (Russian Orthodox Church, Moscow Patriarchate), FGU State Scientific Centre of Social and Forensic Psychiatry named after V.P. Serbskiy. – M., 2006. – 160 p.

Methadone?! (digest based on publication materials) [Electronic resource] / Access code: http://www.aobf.ru/drugs/digest_free.

Declaration of Members of European Cities Against Drugs (ECAD) [Electronic resource] / Access code: http://www.ecad.ru/ecn-doc.html, free.

Tomas Hallberg. "Methadone programme – is a pit" / Speech at the 11th International Conference "AIDS, cancer and related problems", St. Petersburg, 6-10 October 2003 [Electronic resource] / Access code: http://www.ecad.ru/rus-hall_11.html, free.

According to the reports of the European Monitoring Centre for Drugs and Drug Addiction, **in the EU countries where methadone/buprenorphine "substitution therapy" is allowed, growth of lethal poisonings with "prescription" opiates, which include, in the first turn, methadone** is registered.

From 1999 to 2004 **the number of registered death incidents related to methadone usage, increased by 390% in the USA.**[31] The growth of mortality and the number of persons addicted to heroin and prescribed opioids, that is, methadone, too, continues to increase in the USA, and, in the opinion of US Attorney General Eric Holder, this is «an acute crisis in the healthcare system». The latest US anti-narcotic strategy recognizes that during 2010 opioid painkillers including methadone have become the cause of more than 16,600 lethal outcomes due to overdose (approximately 45 incidents per day). This is about 4 times higher than in 2000.

According to the official data, in 2013 in Ukraine 296 (3.3% of the total number of) **"substitution therapy" programmes participants died, 173 participants were deprived of liberty, and only 46 participants (0.5% of the total number) successfully finished "substitution therapy" programmes.** Further fate of "substitution therapy" programmes participants can not be traced, and there is no data on any further remission (duration and quality). **The fate of 1,482 persons who quitted the "substitution therapy" programmes due to various reasons is unknown.** 65.2% of "substitution therapy" programmes participants in Ukraine **are unemployed, 98.8% were not able to complete their education,** 69.1% **do not have families.**[32]

With introduction of methadone "substitution therapy" programmes in **Belarus** this synthetic opium has acquired great "popularity" with drug users. **Thus, in 2004, in the first year of implementation of "substitution therapy" programmes the competent authorities in Belarus seized 3.5 times more methadone than in the similar period in the preceding year.** For comparison: in 2004 there was seized twice less heroin as compared to the similar period in the preceding year.

In Kazakhstan serious attempts to legalize methadone within the framework of implementation of "substitution therapy" for drug addicts have continued for more than 10 years. In November 2010 **professional doctors, narcologists, psychiatrists - were members of the National Medical Association of the Republic of Kazakhstan - sent an open letter to the President of the country Mr Nursultan Nazarbayev** where they **spoke decisively against** implementation of "substitution therapy" programme based on methadone. **193 doctors from various cities in Kazakhstan** signed the

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[31] http://www.cdc.gov/nchs/products/pubs/pubd/hestats/methadone/1999-04/methadone1999-04.htm.

[32] Methadone panacea // Meditsinskaya Gazeta (Medical Newspaper). 11 July 2011. No. (32). P. 6-7.

letter. **Narcologists and psychiatrists informed that patients developed addiction to the daily methadone dose, aggression attacks and suicidal ideas.** Implementation of the programme was accompanied by gross violations of the legislation of the Republic of Kazakhstan regulating narcotic substances circulation. Adversaries of implementation of "substitution therapy" programmes in Kazakhstan found support with a number of officials, Orthodox activists, Muslim leaders, youth and human rights organizations and many ordinary citizens. As a result the plans to increase the number of "substitution therapy" clients from 98 persons (in the cities of Temirtau and Pavlodar) to 3,000 persons were frustrated.[39]

According to the data of ECAD (European Cities against Drugs) **the number of drug users in Lithuania increased by 8 times during the period of implementation of methadone programmes in this country.**

During 9 years of implementation of the methadone programme in Sweden 33% participants of the programme died and 69% continued to commit crimes.

There is no common position in the European Union on the issue of using substitution therapy for treatment for drug addiction. The EU is now at the stage of collecting and analysis of the information on the results of application of this method of drug addiction treatment which is accumulated in the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) located in Lisbon.

Experimental pilot projects for using methadone, including those under the auspices of the World Health Organization (WHO) which pays special attention to this issue, are realized in some countries of Central and Eastern Europe (including Latvia, Lithuania and Poland), in some CIS countries (Georgia, Kyrgyzstan (Kirghizia), Uzbekistan, Ukraine) and in a number of Asian countries (Indonesia, India, Iran, China, Myanmar, Thailand).

In the UN Office on Drugs and Crime (UNODC) there is no single-valued assessment of the effectiveness of substitution therapy as a method of drug addiction treatment, as the countries which are widely using the same are not in a hurry to share with the UN their statistical data in the sphere, due to generally known rather negative attitude of UNODC to this practice.

In 2014 two new constituent entities joined the Russian Federation - the Republic of Crimea and the city with federal status Sevastopol. During the period when these two constituent entities were under Ukrainian jurisdiction "substitution therapy" programmes using methadone and buprenorphine were implemented in their territory. As the result of "substitution therapy" **drug addiction and mortality related to drug use, HIV infection prevalence have significantly (more than two-fold) increased as compared to the Russian**

[39] http://www.odnr.ru/articles/376.htm

Federation. 90% of methadone moved into illicit trafficking,[*] in which the drug users themselves, medical workers were involved, and corruption was flourishing in law enforcement agencies. 65% of "substitution therapy" clients simultaneously continued taking heroin and other drugs.

Moreover, "substitution therapy" participants made repeated attempts to steal methadone and buprenorphine trying to make medical personnel do it by intimidating and threatening them. The premises where "substitution therapy" stations were located had poor sanitary conditions, and disorders constantly took place there.

Almost all participants of "substitution therapy" programmes demonstrated persistent dependent, parasitical attitudes, artificially maintained pathological craving for the drug.

No more than 15% of participants of "substitution therapy" programmes had permanent jobs, no more than 18% had families.[**]

At the present time implementation of "substitution therapy" programmes in the Crimean Federal District has been terminated, all former participants of the programme, except for those who have left for Ukraine (less than 8% of the total number), **having given their informed voluntary consent, have been transferred to Russian treatment and rehabilitation standards. However, no mortality growth among drug addicts have been registered.**

The negative consequences of "substitution therapy" programmes in the Crimea were discussed in the course of a scientific and practical conference. On 9-11 July 2014 a scientific and practical project conference and a meeting with the Chairman of the State Anti-Drug Committee of the Russian Federation on the issue of complex rehabilitation and re-socialization of former participants of "substitution therapy" programmes in the Crimea were held in Yalta. At these events were present the heads and representatives of law enforcement agencies

[*] As noted by Director of the Federal Drug Control Service of Russia V. Ivanov, in the Crimea methadone "was purchased for budget funds, and 90% of the drug was sold in the criminal market. Moreover, methadone was not given out to those who have already become addicted to it. The price of methadone in the market was about one and a half times higher than the price of heroin. That means, in fact, that the Ukrainian budget worked for distribution of drugs... The State had to spend huge amounts from the budget on purchase of the drug which later went to illicit trafficking. At the same time, there was enormous demand for it as a great number of people became addicted to methadone. All these have turned into a giant problem for Ukraine!"

[**] T.V. Klimenko, A.A. Kozlov, P.A. Frolovskiy, A.A. Mandybura. Preliminary assessment of narcological situation, measures for closing substitution therapy programmes for persons with opioid dependence and improvement of narcological service activities in the Republic of Crimea and the city with federal status Sevastopol / Narcology. 2014. No. 5. P. 6-11.

(the Federal Drug Control Service of the Russian Federation, the Federal Service for Execution of Punishments of Russia, the Ministry of the Interior of the Russian Federation), federal and regional executive authorities in the sphere of healthcare, social protection of population, education, youth policy, non-governmental, public and religious organizations, medical specialists (psychiatrists and narcologists) and media. The participants of this event, including those who had been involved in implementation of "substitution therapy" programmes in the Crimea, approved and unanimously adopted the Manifest "No to "substitution therapy" programmes for drug addiction in the Crimea!" in which they condemned the vicious practice of "narcotic ration" disguised as "substitution therapy" and addressed the international community with an appeal to abandon "substitutional therapy" programmes following the example of the Crimea.

No to "substitution therapy" programmes for drug addiction in the Crimea!
Manifest
of the participants of scientific and practical project conference and a meeting with the Chairman of the State Anti-Drug Committee of the Russian Federation on the issue of complex rehabilitation and re-socialization of former participants of "substitution therapy" programmes in the Crimea (Yalta, 9-11 July 2014)

"Substitution therapy" has been known for more than 100 years. **In 1898 a new substance was made by chemical method from morphine - acetylmorphinehydrochloride (heroin) which was tried for treatment of morphine addicts. However, soon it was discovered that heroin itself caused dependence, which was even stronger than the dependence caused by morphine. Hence, that sort of "substitution therapy" was abandoned. The story was repeated in the middle of the 20th century when a synthetic opioid called methadone began to be used for "substitution therapy" of heroin addiction. Obviously, methadone started causing a new type of drug addiction - methadone addiction which had much more difficult clinical course as compared to heroin addiction. And "heroin therapy", which is proposed today as a method for methadone addiction treatment became the apotheosis of "substitution therapy". The vicious circle has closed, emphasizing the absurdity of "substitution therapy" which, as it has turned out, had nothing in common with «therapy», i.e. medical treatment for drug addiction.** However the term has stricken roots, and it still continues to mislead both drug users and their environment, and even narcologists and those representatives of public authorities who make decisions.

In view of the negative results of experiments involving "substitution therapy", methadone was included by the Single Convention on Narcotic Drugs of 1961 in Schedule I - the narcotic drugs subject to the strictest control. The issue of "substitution therapy" was repeatedly discussed at international venues including UN Commission on Narcotic Drugs. It was asserted that substitution of one narcotic drug by another can not be regarded as drug addiction treatment which must be carried out in drug-free atmosphere. It was noted that the majority of "substitution therapy" participants continued to use heroin, whether systematically

or occasionally, that led to lethal overdose growth. It was emphasized that introduction of "narcotic ration" would hinder getting rid of drug abuse. The expectations that distribution of drugs might be used as an "attraction" for drug addicts, with the purpose of creating with them motives for further treatment, have not come true. The population of drug addicts continued to grow, with simultaneous growth of drug-related crimes and getting infected by dangerous infectious diseases which accompany drug addiction.

The Crimea has experienced the disastrous consequences of the Ukrainian authorities' criminal drug circulation policy to the fullest extent possible. **During the period of "substitution therapy" implementation in the territory of the peninsula, drug addiction, HIV infection and mortality among drug addicts have increased considerably in comparison to the Russian Federation. "Substitution therapy" clients, medical personnel, corrupted public officials and Ukrainian law enforcement officers were involved in illicit methadone trafficking.** Organization of narcological aid degraded and was limited to handing out "substitution drugs" in increasing quantities with annual increase of the number of involved population and without any restrictions whatsoever. **"Substitution therapy" of HIV infected persons and persons who had tuberculosis was killing their already weakened immune resistance, however any information related to it was kept secret. As to the "substitution therapy" of pregnant women, it condemned both them and their newly born babies to actually life-long narcotization. An incessant stay in a condition of narcotic intoxication led to increasing degradation of individuality of "substitution therapy" clients, accompanied by social and professional alienation.**

In the Russian Federation, as in most countries of the world, "substitution therapy" of drug addiction is prohibited. The 2004 Memorandum "No to methadone programmes in the Russian Federation! (Use of methadone can not be regarded as treatment)", signed, among other specialists, by RAMN academicians Tatiana Dmitrieva, Aleksandr Tiganov, corresponding RAMN members Nikolay Ivanets, Chairman of the Russian Psychiatrists Union Professor Valeriy Krasnov is widely known. **The international organization European Cities Against Drugs is a consistent adversary of "substitution therapy".**

Only transfer to the Russian standards in the sphere of complex rehabilitation, which became possible after accession of Crimea to the Russian Federation gave to the individuals stabilized by "substitution therapy" in the Crimea hope to get rid of drug dope and to the medical workers - a chance to restore their professional dignity, and to the Crimea as a whole - to set a course for eradication of drug addiction. In the Crimea, "substitution therapy" programmes were terminated by 30 May 2014. The process of their gradual winding up took, on the whole, more than 2 months. It was carried out on the basis of Crimean medical institutions and the best narcological clinics of the Russian Federation, with participation of the leading experts in the field of psychiatry and narcology. **Full compliance with the Russian standards of rendering medical narcological aid, international obligations of the Russian Federation in the humanitarian sphere allowed to avoid complications and increasing mortality among drug users, notwithstanding the harmful consequences of "substitution therapy" for their health.** Those former "substitution therapy" clients who wished to go abroad were given such opportunity.

Nevertheless, **"substitution therapy" lobbyists continue to attack both the Russian Federation and the international drug control system in general; the true aims of such lobbyists are dictated solely by the interests of pharmaceutical companies which manufacture the most dangerous narcotic drugs. They are trying to picture "substitution therapy" as "scientifically justified and effective prevention" of AIDS. There are more and stronger calls in support of legalisation of drugs and application of economic and political sanctions against those countries which counter spreading of methadone and expansion of "substitution therapy" programmes.** Forwardness, ingenuity and obtrusiveness of "substitution therapy" missionaries are increasing. At that, the fate of the suffering people turns into token coin and the States themselves act like drug dealers. A vivid example of such approaches is the report of experts of Perspektiv Group "Substitution maintenance treatment in Ukraine: Humanitarian and medical mission" (16-21 May 2014), based on distorted facts and seeking to interfere into the internal affairs of the Russian Federation.

We, psychiatrists and narcologists, representatives of the State authorities of the Russian Federation, rehabilitation centres, non-government organisations of the Republic of Crimea, city with federal status Sevastopol and other constituent entities of the Russian Federation, call on all interested experts and not indifferent people of Russia, CIS countries and other foreign countries, representatives of competent authorities and international organisations to be alert and to regard with criticism irresponsible statements, full of lies and cynicism, about "substitution therapy" using narcotic drugs as a method of drug addiction treatment, prevention of HIV and AIDS and other infectious diseases, socialization, fighting drug crimes, and regarding the fact that methadone and similar narcotic drugs are "substitution" medicines "vitally important" in case of drug addiction, as well as similar "recommendations" and "standards" which we strongly condemn.

"Substitution therapy" for drug addiction has nothing in common with therapy, i.e. treatment, as it is based on substitution one drug by another one, leading to the most destructive consequences both for the drug addict and the society. "Substitution therapy" for drug addiction worsens the course of dangerous diseases accompanying drug addiction. While not guaranteeing abandoning other drugs, "substitution therapy" increases the risk of lethal overdoses, is accompanied by expansion of criminal drug trafficking, destruction of the system of narcological medical aid, is fraught with accumulation of "the critical mass" of socially maladjusted persons in the society, the behaviour of such persons is depending on the ill-will of those who supply them with "narcotic ration".

Solving the task of complex rehabilitation and resocialisation of drug users including drug addiction treatment is possible only on condition of full termination of drug consumption and forming a healthy and sober lifestyle. It is to this that all interested State institutions and civil society in all the world should direct their efforts.

We call on all countries to follow the Crimean example and to wind up the programmes for "substitution therapy" for drug addiction, where they still exist, and to principal refusal from their implementation in any form whatsoever, including "pilot

projects", "experiments", etc., notwithstanding with whatever reasoning and by whom they are proposed.

[our emphasis added].

Thus, the reasons for the absolute ban on treatment for drug addiction by "substitution therapy" method using methadone and buprenorphine in the Russian Federation are stated above in this Memorandum.

As regards the Court's question whether the absolute ban on drug addiction treatment by "substitution therapy" method using methadone and buprenorphine in the Russian Federation provides for fair balance between the State's obligation to protect the life and health of the persons under its jurisdiction, by way of regulation of access to narcotic substances, on the one part, and the applicants' interest in access to the medicines which could help their cure of drug addiction, on the other part, the Russian Government would like to state the following.

Persons with specific needs in Russia **have access to the medicines which can help them to cure of drug addiction. Such medicines include opioid antagonists and other medicines provided by the Russian standards of rendering medical aid in the sphere of narcology.** In this sense, the fair balance between the said obligation of the State and the applicants' interest in obtaining access to the medicines which could help them to overcome drug addiction has been struck. At the same time, **providing access to narcotic drugs methadone and buprenorphine for the applicants can not "contribute to their recovery from drug addiction" as these narcotic drugs themselves cause or intensify it** (see the evidence in this Memorandum).

As regards the methods of treatment of drug addicted persons used in the Russian Federation and their effectiveness

Narcology as a science, notwithstanding its sectoral independence with regard to psychiatry, is an integral part of psychopathology. Based on the same, it has common (consistent) with psychiatry pathogenetic principles and approaches to treatment of patients.

A large number of psychopharmacotherapeutical medicines (neuroleptics, antidepressants, tranquillisers, anticonvulsants, nootropics), used for treatment of drug addicts is now available. It is noted that they are highly effective if prescribed in a qualified manner.

It should be specially noted that not the diagnosis but the psychopathology which appears in connection with drug abuse or which - as a risk factor - is the reason for appearance of drug addiction is treated with the help of medication.

Along with that, **opiate receptors blockers (naltrexone) which are pathogenetic therapy** - as different from the actively proposed handing over of

methadone or buprenorphine - **are actively used** in Russia for **treatment** of opioid drug addicts.

In addition, **psychotherapeutical, physiotherapeutical methods and a large number of other methods and techniques** in complex therapy format **are used for treatment and rehabilitation** of drug addicts.

Modern approaches to drug addiction treatment were reflected in the Orders of the Ministry of Healthcare of the Russian Federation of 04.09.2012 nos. 124n-135n which constitute Standards for primary specialised and specialised medical assistance in case of dependency diseases.

These approaches imply various stages of rendering medical assistance to dependent patients with acute intoxication, psychoactive substance withdrawal syndrome, in remission, as well as with complications of dependency syndrome. The adopted standards imply complex approach to treatment using various methods, including medication-assisted treatment, detoxication, psychotherapy, physiotherapy, etc. Apart from medical assistance measures included in the standards, there exist additional treatment methods, like therapy using a mixture of xenon and oxygen, extracorporeal detoxication and social rehabilitation which is actively developing in the recent years.

Special attention is paid to rehabilitation issues. On 15.04.2014 the Government of the Russian Federation approved the Sub-programme "Complex Rehabilitation and Resocialization of Persons Using Narcotic Drugs and Psychotropic Substances for Non-Medical Purposes" by their Decree no. 299 "On Approval of the State Programme of the Russian Federation "Combating Illicit Drug Trafficking".

As pointed out by Director of FGBU *National Scientific Narcology Centre* Ye.A. Koshkina, analysis of scientific literature on this topic allows to state that the applied methods of treatment for drug addiction are effective and allow in some cases to achieve long-term remissions lasting many years.

It needs to be noted, too, that **statements about low level of provision of narcological medical aid in the Russian Federation are totally unsubstantiated.** At the present time the reorganization and modernization of the country's narcological service is going on, providing for various measures aimed at improvement of servicing of drug addicted people, including those having accompanying HIV infection.

The State also includes the following to the main measures for increasing effectiveness and development of narcological medical aid: increasing of funding of activities of specialized state narcological institutions in the constituent entities of the Russian Federation, narcological divisions of medical treatment institutions in municipal entities at the expense of budgets of various levels, improvement of methods of treatment of drug addicted persons, regular training of specialists in the sphere of rendering narcological medical aid, increasing of awareness level of specialists in the field of healthcare on the issues of rendering narcological medical aid.

It should be noted that full-fledged treatment for opioid drug addiction, including heroin addiction, in the Russian Federation is built on the principle of individual approach to the patient, attentive and detailed study of the peculiar features of the clinical history of the disease, strict differentiation in choosing medication and building up a treatment programme. Treatment of a drug addict is a difficult task requiring substantial intellectual and material efforts, creative search and clear organization. It is possible to solve the problem only by continuing the search and efforts in order to achieve the best possible results. The course of least resistance with transferring to "substitution therapy" means actual surrender of the State and society in the face of drug addiction, which is a social problem.

The Russian Federation is the only country in the world which has a structured state narcological service which is able to ensure treatment for drug addictions based on unified, scientifically substantiated principles, allowing to follow the path aimed at achievement of the best possible results, without using "substitution therapy" methods hindering rendering narcological aid to the population.

It is worth noting that "effectiveness" of "substitution therapy" is correctly understood and interpreted in a right way in Russia. The so-called **"substitution therapy" has nothing to do with therapy, i.e. treatment.** It is limited to simple handing over of the drug, methadone or buprenorphine, to ill persons. It **deals not with introducing a "medicine to replace the drug" but with replacement of one narcotic drug (heroin) by another one (methadone),[8] it just maintains the disease and leads the drug addict to the inevitable psychic degradation and death.** The acquired practical experience shows that methadone is a highly narcogenic drug which can quickly generate heavy addiction. **Social or any other activity of a drug addict taking methadone is no more than a myth. Using "substitution therapy" is, in fact, the same as alcoholic's constant taking a drop (a drink) for his bad head "the morning after", but for drug addicts. This is not their treatment, but favouring the progress of the disease and its complications.**

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[8] "At the UN Commission on Narcotic Drugs it was repeatedly stated (and now accepted as indisputable fact) that **use of methadone can not be regarded as treatment:** it is merely replacing of one drug by another. Gradually, by 1970 the Commission received data on a large amount of scientific research substantiating the grave consequences of methadone use... As remarked by American scientist Dopps, **«during methadone treatment one drug is merely replaced by another one and does not promote abandoning drugs at all».** It follows that **no drugs whatsoever must be used for treatment of drug addicts, not mentioning such dangerous drug as methadone.** - Cited as per: E.A. Babayan. Use of methadone can not be regarded as treatment // Novaya Apteka. 2002. No. 3. P. 19-22.

The argument that a person taking drugs on a systematic basis is able to lead a proper life is contrary to common sense and practical experience of narcologists. Indeed, long-time use of "substitution therapy" is possible but it is accompanied by substantial limitations in professional activities and worsening of the state of the health. That is why recently arguments in support of "substitution therapy" programmes are mentioned only in respect of their "palliative" use in respect of incurable patients or shifted from the medical sphere to the sphere of protection of a person's right to take drugs if such person does not disturb anyone else. The problem has largely ethical and economic character (as treatment of such patients without narcotic drugs is quite possible but costly and time-consuming, and psychologically it is much simpler to agree to taking "substitution therapy", so far as such proposal comes from a doctor).

"Substitution therapy" as well as the "harm reducing programmes for drug addicted persons" are disguised propaganda of legalization of drugs. Within the framework of these programmes it is stated that safe taking narcotic drugs may be possible. There is no any ideological background in banning "substitution therapy". **From the medical point of view this is a crime, "slowed-down, prolonged euthanasia".**

The experience of using "harm reducing" programmes in the USA and their financing from the federal budget have demonstrated their inefficiveness. In connection with the same the US Congress vetoed funding of these programmes from the federal budget.

As noted by Chief Expert Narcologist of the Ministry of Healthcare of Russia Ye.A. Brun, **the practice of treatment of methadone addicts taking "street" methadone shows that, as compared to heroin addicts, they have more pronounced somatic complications, heavier withdrawal syndrome, and they quicker develop psychical degradation features. This may be explained by larger toxic effect of methadone due to which decrease in immunity and increasing of the existing somatic disorders take place.**

"Lastly, one can not neglect the **disturbing information that methadone accelerates replication (multiplication) of human immunodeficiency virus** and cells infected by HIV produce more viral particles after "treatment" by methadone[39], and **long-term use of methadone by HIV infected persons leads to significantly quicker reduction of lymphocytes count,[40] therefore additionally weakening their immune resistance".[41]**

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[39] Douglas S.D. Methadone may promote HIV replication: study // AIDS Alert. - 2001. - Vol. 16, N 9. - P. 120.

[40] Suzuki S., Carlos M.P., Chuang L.F., Torres J.V., Doi R.H., Chuang R.Y. Methadone induces CCR5 and promotes AIDS virus infection // FEBS Lett. - 2002. - 22; 529, N 3-3. - P. 175-177.

[41] Quang-Cantagrel N.D., Wallace M.R., Adair N., Mallaves C. Long-term methadone treatment: effect on CD4+ lymphocyte counts and HIV-1 plasma RNA level in patients with HIV

In compliance with the published results of clinical research in the USA, China and Sweden from 1985 to 2002, methadone substitution therapy leads to increased HIV replication, weakening immune resistance in form of decreasing monocytes and lymphocytes count (CD4 cells), as well as decreasing CD4/CD8 cells ratio, both in HIV infected patients and patients who had no HIV infection. Based on the results of the analysis of using substitution therapy of HIV-infected drug addicts published by Swedish researchers, it was noted that mortality among HIV-infected patients who received substitution therapy and later by some reasons abandoned the programme was higher than mortality among those patients who never received substitution therapy.[42]

The Russian Government note that **the approach used in Russia, which is aimed at motivation to quit drugs and forming adherence (compliance) to treatment programmes with patients suffering from drug addiction with accompanying HIV infection, allows to increase therapeutic efficacy up to 30-40% of annual remissions in drug addiction and attain stable contact with HIV infection specialists, including forming a conscious approach to taking antiretroviral medicines.**

It needs to be emphasized that **the ban on use of methadone and buprenorphine for treatment for drug addiction allows to provide adequate medical assistance aimed at complete abstaining from drugs.**

Relapses into drug addiction immediately after the treatment (detoxication) are caused by refusal to undergo medical and social rehabilitation which must be effected during sufficiently lengthy periods. **Getting rid of drug addiction is possible only in case of following doctors' recommendations as regards refusal from taking drugs, while failure to follow such recommendations leads to relapses into drug addiction.**

Such failures were intentionally committed by the applicants in the present applications, as the available materials do not contain any information on recognizing them mentally incompetent. Consequently, **total responsibility for risks resulting from similar violations (overdosing problems, low quality of used narcotic drugs, infection by HIV and hepatitis, commission of crimes, impossibility to complete education[43] and**

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infection // Eur. J. Pain. - 2001. - Vol. 5, N 4. - P. 415-428.

[42] http://www.psychiatry.ru/articles/paper132.htm. I.V. Lisitsky. On substitution therapy for drug addicts using methadone - among other things.

[43] Fugelstad A., Rajs J., Bottiger M., Gerhardsson de Verdier M. Mortality among HIV-infected intravenous drug addicts in Stockholm in relation to methadone treatment // Addiction. - 1993. - Vol. 90, no. 5. - P. 711-716.

[43] **A.V. Karmanayevskiy**, born on 23.02.1985, studied at secondary school no. 18 with advanced curriculum in English of the Vakhitovskiy District of the city of Kazan from 01.09.1997 till 05.09.1995. According to order of 06.09.1995 no. 72 he left it for the Kazan cooperative college. On 30.10.1997 he was enlisted into the 10th grade of open (evening)

retain jobs[43], family relations[44]) is to be borne by the applicants themselves. However, it is worth noting that the applicants work (worked), two applicants

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school no. 12 of the Yukhnovsky District of the city of Kazan. On 03.03.1998 he was expelled from the educational institution due to illness (order of 03.03.1998 no. 2).

I.N. Teplinskaya (**Abdyrakhova**), born on 22.10.1964, graduated from secondary school no. 23 of the city of Kaliningrad (now MAOU Lyceum no. 23) in 1984. From 01.09.1984 to 01.09.1989 she studied at the Novosibirsk Mechanical Engineers Institute. By order of 16.09.1985 no. 947 I.N. Teplinskaya was transferred to the second grade of full-time course of engineering and economic faculty, *specialty* "Economics and organization of food industry" of the Kaliningrad Technical Fish Industry and Business Institute. By order of 11.02.1988 no. 101d I.N. Teplinskaya was expelled from the Institute for academical failure. (Source: I.N. Teplinskaya's personal file).

On 28.08.1988 **I.V. Anokhin** was enlisted into the second class of school no. 65 of the city of Togliatti, on 17.06.1994 he left it for Vocational School no. 45 of Togliatti, from 15.06.1995 to 01.07.1998 he studied at Vocational School no. 11, where he received primary vocational education in the profession of electric and gas welder with assigning of II grade.

[43] **A.V. Kurmanayevskiy** has been working in GBOU VPO Kazan State Medical University since 02.02.1998 till the present moment (since 10.09.2001 – as corporate of anatomical theatre). His monthly salary is RUB 7,525.16. Besides, according to the information on the Internet and in social networks he deals with original crotch cuttings in OOO "AlCor" (20, Orenburgskiy trakt str., Kazan, office 302). The applicant owns Audi A2 car, during the recent two years he has visited Brazil, Thailand, the USA, Holland, Ukraine and Lithuania. In this way, A.V. Kurmanayevskiy has a permanent job, permanent income and wages, is well-off.

According to the data provided by the department of the Pension Fund of the Russian Federation for the Kaliningrad Region, **I.N. Abdyrakheva** was allocated contributions for the insurance part of her pension for the period from 13.11.2008 till 31.12.2012, including from the Foundation for Promotion of Healthcare and Social Justice named after Andrey Rylkov (hereinafter – "the Foundation") from 01.10.2010 till 31.12.2012. According to the natural person income certificate, provided by Inter-District Inspectorate no. 8 of the Federal Tax Service for the city of Kaliningrad, in 2012 I.N. Abdyrakheva received from the Foundation the total income amounting to RUB 143,428.57. Therefore, before 2013 I.N. Abdyrakheva has been working.

I.V. Anokhin worked at various companies and enterprises in Togliatti from 01.06.2004 to 12.12.2011, however he worked less than a year in every place and quit the jobs on his own will. From 12.12.2011 till 01.10.2013 he did not work anywhere as in this period he was taking drugs, and he lived with his mother who supported him. From 01.10.2013 till the present time he has been working as a social worker in Autonomous non-commercial organization for social support of population "April Project" and receives a monthly salary in the amount of RUB 4,950.

[44] **A.V. Kurmanayevskiy** has a son and is married. In the electronic kind of official records of births, deaths and marriages of the Republic of Tatarstan there are the following

have children, one is married, one has received primary professional education (see the information in the footnotes in this paragraph of the Memorandum).

Therefore, the applicants' complaints against hindering effective treatment for drug addiction and violation of the right to respect for their private life are ill-founded. On the contrary, "substitution therapy" using methadone and buprenorphine, which cause or deepen drug addiction could be an obstacle for effective treatment for drug addiction.

As regards absence of violation of A.V. Kurmanayevskiy's rights

Taking the procedural decisions in the case of A.V. Kurmanayevskiy the courts of the first and cassational instance based on the requirements of Article 41 of the Constitution of the Russian Federation, Article 20 of *the Fundamentals of the Legislation of the Russian Federation on the Protection of Citizens' Health*, Article 35 of the Federal Law of 08.01.1998 no. 3-FZ *On Narcotic Drugs and Psychotropic Substances*, the Decree of the Government of the Russian Federation of 30.06.1998 no. 681 *On Approval of the Index of Narcotic Drugs, Psychotropic Substances and their Precursors subject to Control in the Russian Federation*, including **taking into consideration the provisions guaranteeing rendering medical narcological aid to drug addicts and providing the treatment, impossibility of use of narcotic drugs prohibited for circulation.**

Therefore, A.V. Kurmanayevskiy's rights were not violated in this case.

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records in respect of A.V. Kurmanayevskiy: about the birth of his son Arseniy Aleksandrovich Kurmanayevskiy, born on 19.04.2005 (no. 317 of 27.05.2005 of the Civil Registry Office department of the Administration of the Moskovskiy District of Kazan), the child's mother – Elida Anvarovna Shakirova, born on 15.02.1981; on establishment of paternity in respect of son Arseniy (no. 72 of 27.05.2005 of the Civil Registry Office department of the Administration of the Moskovskiy District of Kazan); on marriage with Mariya Borisovna Ginzburg (name after marriage – Kurmanayevskaya), born on 01.04.1983 in Kazan, Republic of Tatarstan (no. 287 of 25.07.2008 of the Civil Registry Office department of the Executive Committee of the Municipal Entity of Kazan).

I.V. Anokhin has a son. In the archive of the Civil Registry Office of the Central District of the city circuit of Togliatti of the Civil Registry Office Department for the Samara Region there are entries about birth (no. 1078 of 02.08.2005, on establishment of paternity no. 179 of 02.08.2005, drawn up in respect of Vladislav Ivanovich Anokhin (name before establishment of paternity – Larionov), born on 25.07.2005, the indicated names of the parents are: father – Ivan Vasilyevich Anokhin, born on 05.02.1980, mother – Olesia Nikolayevna Larionova, born on 10.11.1979.

As regards absence of violation of I.N. Abdyusheva's rights

As indicated above in this Memorandum (see the section "Circumstances of the cases") the reply to the applicant's application to the Ministry of Healthcare of the Kaliningrad Region of 11.01.2011 was given in the letter of the Chief Doctor of OGBUZ "Regional Narcological Hospital" of 27.01.2011, ref. no. 172 where as the reason for the refusal to prescribe medical treatment by the method of opioid "substitution therapy" using methadone or buprenorphine the ban on treatment for drug addiction using methadone and buprenorphine in the Russian Federation, in compliance with Federal Law of the Russian Federation of 08.01.1998 no. 3-FZ *On Narcotic Drugs and Psychotropic Substances* was indicated. **Along with that, it was advised to the applicant to consult the Dispensary Department of the Regional Narcological Hospital in order to obtain information on modern methods of opioid drug addiction treatment and prescribing her the necessary medication.**

The Government of the Russian Federation believe that **I.N. Abdyusheva's right to obtaining the necessary free medical aid, provided by Article 41 of the Constitution of the Russian Federation, was not violated in any way. It was offered** to I.N. Abdyusheva **to undergo treatment by allowed methods, but she insisted on the method prohibited in the Russian Federation.**

Article 55 § 4 of the Federal Law of 08.01.1998 no. 3-FZ *On Narcotic Drugs and Psychotropic Substances* provides that **diagnosing of drug addiction and treatment of drug addicts shall be effected applying only those means and methods which are allowed for the relevant purposes by the federal executive authority in the sphere of health protection.**

As established by the decision of the Leningradskiy District Court of the city of Kaliningrad of 27.05.2011, "as drug addiction treatment using methadone and buprenorphine is prohibited in the Russian Federation by the valid Russian legislation, the refusal of the Ministry of Healthcare of the Kaliningrad Region, OGBUZ "Regional Narcological Hospital" to prescribe the applicant treatment using methadone or buprenorphine is lawful, therefore the rights and freedoms of the applicant are not violated by it".

As regards absence of violation of I.V. Anoshkin's rights

I.V. Anoshkin's arguments alleging violation of his constitutional right to medical aid are based on the fact that he was refused treatment by the method of opioid substitution (supporting) therapy using methadone or buprenorphine, however Federal Law of 08.01.1998 no. 3-FZ *On Narcotic Drugs and Psychotropic Substances* classifies methadone and buprenorphine as narcotic drugs prohibited for circulation in the Russian Federation.

Refusing to prescribe the said method to the applicant the Ministry of Healthcare and Social Development of the Samara Region acted in accordance with law, exercising its authority for determination of the procedure of rendering medical aid.

In view of the aforementioned the Government of the Russian Federation declare that I.V. Anoshkin was refused not medical aid and not treatment for drug addiction, he was refused treatment by the method using narcotic drugs banned for circulation by the valid legislation, which in the present case can not be recognized as contradicting the provisions of the Constitution of the Russian Federation.

Therefore, **I.V. Anoshkin's rights to receiving medical aid were not violated as the Ministry of Healthcare and Social Development of the Samara Region recommended him to continue treatment and medical and social rehabilitation in the Togliatti Narcological Dispensary in compliance with the existing standards of drug addicts treatment,** approved by the Order of the Ministry of Healthcare of the Russian Federation of 28.04.1998 no. 140 and the procedure for rendering narcological aid to the population of the Russian Federation approved by the Order of the Ministry of Healthcare and Social Development of the Russian Federation of 09.04.2010 no. 225an.

I.V. Anoshkin's unwillingness to undergo treatment using the treatment methods approved by the duly authorized executive body may not serve as the grounds for prescribing him treatment using methadone or buprenorphine, which are prohibited for circulation in the Russian Federation and does not evidence any violation of his constitutional rights.

In support of their position the Government of the Russian Federation would like to refer to the European Court's case-law, in particular the judgment in the case of *Hristozov and Others v. Bulgaria*, nos. 47039/11 and 358/12, 13 November 2012, the provisions of which, in the opinion of the Government of the Russian Federation, are in many aspects applicable to the examined cases of A.V. Karmanovskiy, I.N. Abdyusheva, I.V. Anoshkin.

In the case of *Hristozov and Others v. Bulgaria* the applications were lodged by ten Bulgarian nationals, the first applicant on application no. 47039/11 and all the eight applicants on application no. 358/12 have or had various types of incurable cancer. Having undergone traditional treatment (including surgery, chemiotherapy, radiotherapy and hormone therapy), or having obtained a medical expert statement that such forms of medical treatment would not work in their cases or were not available in Bulgaria, they applied to a private clinic in Sofia where they learned about experimental anti-cancer medicine developed by a Canadian company which was not allowed in any country yet. They applied for a permit to use this product, but received a refusal from the Medicines Executive Agency - the authority responsible for

supervision of the quality, safety and effectiveness of medical products, - which referred to the fact that the said product was an experimental one, not allowed for use as it had not undergone clinical trials in any country, meaning that it could not be allowed for use in Bulgaria in compliance with Regulations of 10 January 2001 no. 2.

In the said judgment the Court noted that «the Court's task in cases arising from individual applications is not to review domestic law in the abstract, but to examine the manner in which that law has been applied to the applicants (see, among other authorities, *McCann and Others v. the United Kingdom*, 27 September 1995, § 153, Series A no. 324; *Pham Hoang v. France*, 25 September 1992, § 33, Series A no. 243; *Sommerfeld v. Germany* [GC], no. 31871/96, § 86, ECHR 2003-VIII; and *S.H. and Others v. Austria* [GC], no. 57813/00, § 92, ECHR 2011-...)... **It is therefore not called upon in the present case to pass judgment on the system of rules governing access to unauthorised medicinal products in Bulgaria, or to decide whether refusal of access to medicinal products is in principle compatible with the Convention. Moreover, the Court is not competent to express an opinion as to the suitability of a particular medical treatment.** Lastly, the Court does not have to establish whether the product that the applicants wished to use met the requirements of European Union law, and in particular the requirement of Article 83 § 2 of Regulation (EC) no. 726/2004 to be undergoing clinical trials (see paragraphs 10, 45 and 50 above); **the Court is competent only to apply the Convention**, and it is not its task to review compliance with other international instruments (see *Di Giovine v. Portugal* (dec.), no. 39912/98, 31 August 1999; *Hermida Paz v. Spain* (dec.), no. 41660/02, 28 January 2003; *Somogyi v. Italy*, no. 67972/01, § 62, ECHR 2004-IV; *Calheiros Lopes and Others v. Portugal* (dec.), no. 69038/01, 3 June 2004; and *Böheim v. Italy* (dec.), no. 35666/05, 22 May 2007). **In the present case, the Court must determine only whether the refusals to allow the applicants access to the product at issue were compatible with their Convention rights»**[45] (§ 105 of the judgment).

«Although the boundaries between the State's positive and negative obligations under Article 8 do not lend themselves to precise definition, the applicable principles are similar. In both contexts regard must be had to the fair

[45] «The Court's task in cases arising from individual applications is not to review domestic law in the abstract, but to examine the manner in which that law has been applied to the applicants (see, among other authorities, *McCann and Others v. the United Kingdom*, 27 September 1995, § 153, Series A no. 324; *Pham Hoang v. France*, 25 September 1992, § 33, Series A no. 243; *Sommerfeld v. Germany* [GC], no. 31871/96, § 86, ECHR 2003-VIII; and *S.H. and Others v. Austria* [GC], no. 57813/00, § 92, ECHR 2011-...)... **It is therefore not called upon in the present case to pass judgment on the system of rules governing access to unauthorised medicinal products in Bulgaria, or to decide whether refusal of access to**

balance that has to be struck between the competing interests of the individual and of the community as a whole (see, among other authorities, *Powell and Rayner v. the United Kingdom*, 21 February 1990, § 41, Series A no. 172; *Evans v. the United Kingdom* [GC], no. 6339/05, § 75, ECHR 2007-I; and *Dickson v. the United Kingdom* [GC], no. 44362/04, § 70, ECHR 2007-V)»[46] (§ 117 of the judgment).

The Court noted that «**matters of health-care policy are in principle within the margin of appreciation of the domestic authorities**, who are best placed to assess priorities, use of resources and social needs (see *Shelley v. the United Kingdom* (dec.), no. 23800/06, 4 January 2008)»[47] (§ 119 of the judgment).

«The Court concluded that **the margin of appreciation to be afforded to the respondent State must be a wide one, especially as regards the detailed rules it lays down with a view to achieving a balance between competing**

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medicinal products is in principle compatible with the Convention. Moreover, the Court is not competent to express an opinion as to the suitability of a particular medical treatment. Lastly, the Court does not have to establish whether the product that the applicants wished to use met the requirements of European Union law, and in particular the requirement of Article 83 § 2 of Regulation (EC) no. 726/2004 to be undergoing clinical trials (see paragraphs 10, 45 and 50 above); **the Court is competent only to apply the Convention**, and it is not its task to review compliance with other international instruments (see *Di Giovine v. Portugal* (dec.), no. 39912/98, 31 August 1999; *Hermida Paz v. Spain* (dec.), no. 41660/02, 28 January 2003; *Somogyi v. Italy*, no. 67972/01, § 62, ECHR 2004-IV; *Calheiros Lopes and Others v. Portugal* (dec.), no. 69038/01, 3 June 2004; and *Böheim v. Italy* (dec.), no. 35666/05, 22 May 2007). **In the present case, the Court must determine only whether the refusals to allow the applicants access to the product at issue were compatible with their Convention rights».**

[46] «Although the boundaries between the State's positive and negative obligations under Article 8 do not lend themselves to precise definition, the applicable principles are similar. In both contexts regard must be had to the fair balance that has to be struck between the competing interests of the individual and of the community as a whole (see, among other authorities, *Powell and Rayner v. the United Kingdom*, 21 February 1990, § 41, Series A no. 172; *Evans v. the United Kingdom* [GC], no. 6339/05, § 75, ECHR 2007-I; and *Dickson v. the United Kingdom* [GC], no. 44362/04, § 70, ECHR 2007-V)».

[47] «**Matters of health-care policy are in principle within the margin of appreciation of the domestic authorities**, who are best placed to assess priorities, use of resources and social needs (see *Shelley v. the United Kingdom* (dec.), no. 23800/06, 4 January 2008)».

public and private interests (see, *mutatis mutandis*, *Evans*, § 82, and *S.H. and Others v. Austria*, § 97, both cited above)»[48] (§ 124 of the judgment).

The Court found that «the Bulgarian authorities have chosen to balance the competing interests by allowing patients who cannot be satisfactorily treated with authorised medicinal products, including terminally ill patients such as the applicants, to obtain, under certain conditions, medicinal products which have not been authorised in Bulgaria, but only if those products have already been authorised in another country... That was apparently the main reason for the refusals by the Medicines Executive Agency in the applicants' cases... **Such a solution tilts the balance between potential therapeutic benefit and medicine risk avoidance decisively in favour of the latter, because medicinal products authorised in another country are likely already to have been subjected to comprehensive safety and efficacy testing. At the same time, this solution leaves products which are still in the various stages of development entirely inaccessible. In view of the authorities' broad margin of appreciation in this domain, the Court considers that regulatory solution did not fall foul of Article 8. It is not for an international court to determine in place of the competent national authorities the acceptable level of risk in such circumstances. The salient question in terms of Article 8 is not whether a different solution might have struck a fairer balance, but whether, in striking the balance at the point at which they did, the Bulgarian authorities exceeded the wide margin of appreciation afforded to them** (see, *mutatis mutandis*, *Evans*, § 91, and *S.H. and Others v. Austria*, § 106, both cited above). In view of the considerations set out above, the Court is unable to find that they did.

The applicants' other criticism of the regulatory arrangement **was that it did not sufficiently allow individual circumstances to be taken into account**. However, the Court finds that this was not necessarily inconsistent with Article 8. **It is not in itself contrary to the requirements of that provision for a State to regulate important aspects of private life without making provision for the weighing of competing interests in the circumstances of each individual case** (see, *mutatis mutandis*, *Pretty*, §§ 74-76; *Evans*, § 89; and *S.H. and Others v. Austria*, § 110, all cited above).

The Court therefore concludes that there has been no violation of Article 8 of the Convention»[49] (§§ 125-127).

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[48] «The Court concluded that **the margin of appreciation to be afforded to the respondent State must be a wide one, especially as regards the detailed rules it lays down with a view to achieving a balance between competing public and private interests** (see, *mutatis mutandis*, *Evans*, § 82, and *S.H. and Others v. Austria*, § 97, both cited above)».

[49] «The Bulgarian authorities have chosen to balance the competing interests by allowing patients who cannot be satisfactorily treated with authorised medicinal products, including terminally ill patients such as the applicants, to obtain, under certain conditions,

[our emphasis added]

In view of the aforementioned, the Government of the Russian Federation believe that the conclusions as to the absence of violation of Article 8 of the Convention made by the European Court in the aforementioned judgment are applicable, by analogy, to the cases of applicants A.V. Kurmasayevskiy, I.N. Abdyrakhova, I.V. Anoshkin.

Moreover, taking into consideration that the case of *Hristozov and Others v. Bulgaria* concerns the refusal of treatment of terminally ill patients by the medical product which has not undergone trials and has not been allowed for use by the competent national authorities. While the present cases concern three persons suffering from drug addiction who have been refused the "treatment" by narcotic drugs prohibited for use in the Russian Federation, and these persons **have not been deprived of the opportunity to receive** in the Russian Federation free **medical treatment by allowed medicines in compliance with the Russian standards of providing medical aid in the sphere of narcology.**

In the decision in the case of *Rodiena Fedosejeva v. Latvia* (no. 37546/06, decision of 19 November 2013) the Court noted that: «**the applicant's**

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medicinal products which have not been authorised in Bulgaria, but only if those products have already been authorised in another country... That was apparently the main reason for the refusals by the Medicines Executive Agency in the applicants' cases... Such a solution tilts the balance between potential therapeutic benefit and medicine risk avoidance decisively in favour of the latter, because medicinal products authorised in another country are likely already to have been subjected to comprehensive safety and efficacy testing. At the same time, **this solution leaves products which are still in the various stages of development entirely inaccessible. In view of the authorities' broad margin of appreciation in this domain, the Court considers that regulatory solution did not fall foul of Article 8. It is not for an international court to determine in place of the competent national authorities the acceptable level of risk in such circumstances. The salient question in terms of Article 8 is not whether a different solution might have struck a fairer balance, but whether, in striking the balance at the point at which they did, the Bulgarian authorities exceeded the wide margin of appreciation afforded to them** (see, *mutatis mutandis*, *Evans*, § 91, and *S.H. and Others v. Austria*, § 106, both cited above). **In view of the considerations set out above, the Court is unable to find that they did.**

The applicants' other criticism of the regulatory arrangement **was that it did not sufficiently allow individual circumstances to be taken into account**. However, the Court finds that this was not necessarily inconsistent with Article 8. **It is not in itself contrary to the requirements of that provision for a State to regulate important aspects of private life without making provision for the weighing of competing interests in the circumstances of each individual case** (see, *mutatis mutandis*, *Pretty*, §§ 74-76; *Evans*, § 89; and *S.H. and Others v. Austria*, § 110, all cited above).

The Court therefore concludes that there has been no violation of Article 8 of the Convention.

dissatisfaction with the medical care afforded to him in detention **largely lies in the fact that he did not receive adequate treatment** for his HIV infection. **However, the Court cannot establish whether the applicant in fact required** any particular treatment (for example, antiretroviral treatment), **since it is not its task to rule on matters lying exclusively within the field of expertise of medical specialists**[10] (§ 49).

[our emphasis added]

In the decision in the case of *Valentina Pentiacova and Others v. Moldova* (no. 14462/03, decision of 4 January 2005) the Court pointed out: «In the present case the Court notes **that the applicants had access to the standard of health care offered to the general public** both before and after the implementation of the medical care system reform. It **thus appears that they were provided with basic medical care and basic medication** before 1 January 2004, and have been provided with almost full medical care after that date. The Court by no means wishes to minimise the difficulties apparently encountered by the applicants and appreciates the very real improvement which a total haemodialysis coverage would entail for their private and family lives. **Nevertheless, the Court is of the opinion that in the circumstances of the present case it cannot be said that the respondent State failed to strike a fair balance between the competing interests of the applicants and the community as a whole**».[11]

[our emphasis added]

Taking into consideration the totality of the arguments stated above in the present Memorandum the Government of the Russian Federation declare that **the refusal to prescribe treatment for drug addiction by the method of**

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[10] «**The applicant's dissatisfaction with the medical care afforded to him** in detention **largely lies in the fact that he did not receive adequate treatment** for his HIV infection. **However, the Court cannot establish whether the applicant in fact required any particular treatment** (for example, antiretroviral treatment), **since it is not its task to rule on matters lying exclusively within the field of expertise of medical specialists**».

[11] «In the present case the Court notes **that the applicants had access to the standard of health care offered to the general public** both before and after the implementation of the medical care system reform. **It thus appears that they were provided with basic medical care and basic medication** before 1 January 2004, and have been provided with almost full medical care after that date. The Court by no means wishes to minimise the difficulties apparently encountered by the applicants and appreciates the very real improvement which a total haemodialysis coverage would entail for their private and family lives. **Nevertheless, the Court is of the opinion that in the circumstances of the present case it cannot be said that the respondent State failed to strike a fair balance between the competing interests of the applicants and the community as a whole**».

opioid substitution (supporting) therapy using methadone or buprenorphine does not violate the right of applicants A.V. Karmazayevskiy, I.N. Abdyushova, I.V. Anokhin **to respect for their private life guaranteed by Article 8 of the Convention for the Protection of Human Rights and Fundamental Freedoms**.

4. Answer to question no. 2 posed by the Court.

Were the applicants subjected to discrimination in connection with their health state (Kiyutin v. Russia, no. 2700/10 of 10 March 2011, § 57) in violation of Article 14 of the Convention, taken in conjunction with Article 8 of the Convention, in connection with a ban on drug addiction treatment using methadone and buprenorphine, as provided for by Article 31 §§ 1, 6 of the Federal Law On Narcotic Drugs and Psychotropic Substances?

The Government of the Russian Federation declare that **the applicants were not subjected to discrimination in connection with their health state in violation of Article 14 of the Convention, taken in conjunction with Article 8 of the Convention, in connection with a ban on drug addiction treatment using methadone and buprenorphine, as provided for by Article 31 §§ 1, 6 of the Federal Law *On Narcotic Drugs and Psychotropic Substances*.**

The Government of the Russian Federation note that use of methadone and buprenorphine which causes mental and behavioural disorders (drug addiction, dependency syndrome, withdrawal syndrome, etc.) presents danger to man and society, violates individuals' right to the highest possible achievable level of physical and mental health. **Persuading people to using methadone and buprenorphine disguised as "substitution therapy" violates their right to obtaining information about the circumstances which create danger for their life or health** (Article 257 of the Criminal Code of the Russian Federation), which in turn violates the freedom of choice by the individuals of their health protection (Article 23 § 1 of the Federal Law of 21.11.2011 no. 323-FZ, amended as of 28.12.2013, amended as of 04.06.2014 *On the Fundamental Principles of Protection of the Health of the Citizens in the Russian Federation*), as well as law-abiding behaviour.

The ban on "treatment" for drug addiction using methadone and buprenorphine is aimed at protection of the said rights and freedoms.

In the Russian Federation, any willing person can obtain free full-fledged treatment for drug addiction including detoxication, correction of psychic and behavioural disorders, medical and social rehabilitation as well as anti-relapse treatment with the help of opioid antagonists. Such treatment is easily accessible to anybody and only it, subject to observation of medical recommendations, allows to achieve remission (refusal from

taking drugs), full-fledged labour and social recovery. Such things are not possible in case of using methadone and buprenorphine.

The demarcation between drug addicted persons suffering from chronic disease and other persons suffering from various chronic diseases, such as persons suffering from insulin dependent diabetes or cancer is not discrimination but differential diagnostics between absolutely different (in terms of origin, development and manifestation) diseases, which results in absolutely different, differentiated treatment methods.

Suffering from mental and behavioural disorders connected with drug use (dependency syndrome, withdrawal syndrome and others) can be avoided only in case of complete refusal from such use. Switching to use of methadone and buprenorphine under the veil of medical treatment does not allow to achieve it as the said mental and behavioural disorders remain and may increase in this case.

Within the framework of the national legislation it was repeatedly suggested to A.V. Kurmanayevskiy, I.N. Abdyusheva and I.V. Anokhkin to undergo full-fledged drug addiction treatment including de-toxication, correction of mental and behavioural disorders, medical and social rehabilitation as well as anti-relapse treatment with opioid antagonists. This treatment, aimed at achieving sober and healthy lifestyle is available to anybody in the Russian Federation and is free for all its nationals wishing to undergo such treatment. However the guarantee of successful effecting of such treatment is observation of medical recommendations as well as the will and wish of a drug addicted person to get rid of drug abuse.

After beginning of rendering medical "aid" the applicants neglected medical recommendations for undergoing full treatment course including recommendation to give up taking drugs, as a consequence the applicants had the relapses into drug addiction.

In connection with the above-mentioned A.V. Kurmanayevskiy, I.N. Abdyusheva and I.V. Anokhkin were not subjected to discrimination in connection with their health state.

"Substitution therapy" is discrimination in itself, as it is a surrogate form of medical aid which condemns its participants to actual life-long narcotization destroying a person's individuality in violation of his or her inherent right to health protection and the highest achievable level of physical and mental health.

Discrimination is also manifested through concealment of truth from "substitution therapy" clients or distortion of the truth about its negative consequences and the risks it entails for human health and life, when such form of legalization of harmful drugs is presented as drug addiction treatment.

It is worth noting that drug addiction treatment in the Russian Federation is effected by highly qualified medical specialists: psychiatrist-

narcologists, as different from the majority of those countries where "substitution therapy" is practised which is normally realised by general practitioners or nursing staff (and it may also be regarded as discrimination - so far as access to specialised treatment is concerned).

Moreover, in connection with the said question posed by the Court as to whether the applicants were subjected to discrimination on account of the state of their health in violation of Article 14 of the Convention in conjunction with Article 8 of the Convention, it is worth noting in particular that **the method of treatment for drug addiction using methadone and buprenorphine is prohibited in the territory of the Russian Federation for all persons without any exceptions and - we put special emphasis on that - notwithstanding the state of their health. Therefore, in this case there is no and there can not be any discrimination in respect of the three applicants in connection with the state of their health. They can receive in Russia the same treatment as other drug addicted persons.**

As that, the Government of the Russian Federation emphasize that the Court's judgment in *Kiyutin v. Russia* (no. 2700/10, of 10 March 2011) is inapplicable to the present cases of the applicants. "The Court has established in its case-law that **discrimination means treating differently, without an objective and reasonable justification, persons in analogous, or relevantly similar, situations** (*see D.H. and Others v. the Czech Republic* [GC], no. 57325/00, § 175, ECHR 2007, and *Burden v. the United Kingdom* [GC], no. 13378/05, § 60, ECHR 2008-...)"[2] (§ 59 of the judgment).

[our emphasis added]

In *Kiyutin v. Russia* the HIV infected applicant who was a national of Uzbekistan complained against the refusal of the territorial division of the Federal Migration Service of Russia to issue him a permit for temporary residence in the Russian Federation. The Court found that the applicant has been a victim of discrimination on account of his health status. However, in the present cases the HIV infected applicants are nationals of the Russian Federation, enjoy all the rights and freedoms, are not subjected to discrimination in connection with the state of their health and, as other Russian nationals, have the right to receive the relevant treatment in compliance with the existing legislation of the Russian Federation.

In the context of the attempts to impose upon the Russian Federation implementation of "substitution therapy" as a measure for prevention of HIV infection the Russian Government would like to refer to the provisions of the

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[2] «The Court has established in its case-law that **discrimination means treating differently, without an objective and reasonable justification, persons in analogous, or relevantly similar, situations** (*see D.H. and Others v. the Czech Republic* [GC], no. 57325/00, § 175, ECHR 2007, and *Burden v. the United Kingdom* [GC], no. 13378/05, § 60, ECHR 2008-...)».

Political Declaration on HIV/AIDS of 2011 (adopted by Resolution no. 65/277 of the General Assembly of 10 June 2011), in compliance with which Heads of State and Government and representatives of States and Governments who assembled at the United Nations from 8 to 10 June 2011, reaffirmed the sovereign rights of Member States, as enshrined in the Charter of the United Nations, and the need for all countries to implement the commitments and pledges in the present Declaration consistent with national laws, national development priorities and international human rights;

recognized that, although HIV and AIDS are affecting every region of the world, each country's epidemic is distinctive in terms of drivers, vulnerabilities, aggravating factors and the populations that are affected, and therefore the responses from both the international community and the countries themselves must be uniquely tailored to each particular situation, taking into account the epidemiological and social context of each country concerned (§§ 2, 4).

Based on the aforementioned, the Russian Government emphasizes that **applicants A.V. Karmazayevskiy, I.N. Abdyushova, I.V. Anokhkin were not subjected to any discrimination in the field of health protection and obtaining medical aid. The refusal to prescribe drug addiction treatment by the method of opioid substitution (supporting) therapy using methadone or buprenorphine does not violate the applicants' rights guaranteed by Article 14 of the Convention for the Protection of Human Rights and Fundamental Freedoms.**

Moreover, the Government of the Russian Federation also draw the attention of the European Court to the fact that **the applicants' problem actually is of a single, individual character.** In substantiation of this we hereby inform that **according to the information,** received in the process of preparation of this Memorandum **from the Supreme Court of the Republic of Tatarstan, the Kaliningrad Regional Court, the Samara Regional Court, no statements of other individuals suffering from drug addiction on contesting the actions (omission) of healthcare authorities, expressed in the refusal to prescribe to them treatment by "substitution therapy" method using methadone or buprenorphine have been received, accordingly, by the courts of the Republic of Tatarstan, the Kaliningrad Region or the Samara Region.**

5. Conclusion

Summing up everything which is stated above in this Memorandum in connection with the examined applications the Government of the Russian Federation would like to note the following:

- Methadone and buprenorphine are narcotic drugs of opioid group which cause development of mental and behavioural disorders. **Use of methadone and buprenorphine in case of drug addiction caused by taking other opioids** (opium, heroin, etc.) **increases the aforementioned mental and behavioural disorders. At the same time, the risk of lethal overdoses is increased.** Using the narcotic drugs methadone and buprenorphine in case of drug addiction caused by taking other narcotic substances leads to development of poly-drug use. In addition, mental and behavioural disorders deepen as well. Thus, **replacement of other narcotic drugs by methadone and buprenorphine must be regarded not as a method for treatment for drug addiction but as legalisation of drug abuse.** "Substitution therapy" as well as the "harm reducing programmes for drug addicted persons" are **disguised propaganda of legalisation of drugs.** Within the framework of these programmes it is stated that safe taking narcotic drugs may be possible. There is no any ideological background in banning "substitution therapy". **From the medical point of view this is a crime, "slowed-down, prolonged euthanasia".**
- **The refusal to prescribe treatment for drug addiction by the method of opioid "substitution (supporting) therapy" using methadone or buprenorphine does not violate the right of A.V. Karmazayevskiy, I.N. Abdyushova, I.V. Anokhkin to respect for their private life guaranteed by Article 8 of the Convention.** The applicants' complaints against hindering effective treatment for drug addiction and violation of the right to respect for their private life are ill-founded. **On the contrary, "substitution therapy" using methadone and buprenorphine, which cause or deepen drug addiction could be an obstacle for effective treatment for drug addiction.**
- **Persons with specific needs in Russia have access to the medicines which can help them to cure of drug addiction. Such medicines include opioid antagonists and other medicines provided by the Russian standards of rendering medical aid in the sphere of narcology. Providing access to narcotic drugs methadone and buprenorphine for the applicants can not "contribute to their recovery from drug addiction" as the said narcotic drugs themselves create or increase drug addiction.**
- **The argument that the methods of drug addiction treatment existing in the Russian Federation do not yield any results is refuted by the information about the treatment of A.V. Karmazayevskiy, obtained from the Ministry of Healthcare of the Republic of Tatarstan: using the methods of treatment and rehabilitation of drug addiction permitted in the Russian Federation allowed A.V. Karmazayevskiy to reach remission which lasts**

about 4 years (as of 14.07.2014).

- In connection with the applicants' complaints alleging violation of the right to respect for their private life guaranteed by Article 8 of the Convention, the Government of the Russian Federation emphasize that **use of "substitution therapy" does not mean that a person will be able to work, study and have a normal family**. The argument that a person taking drugs on a systematic basis is able to lead a proper lifestyle is contrary to common sense and practical experience of narcologists. The acquired practical experience shows that methadone is a highly narcogenic drug which can quickly generate heavy addiction. **Social or any other activity of a drug addict taking methadone is no more than a myth.** At the same time, it should be noted that the applicants, being absolutely legally capable, must themselves bear full responsibility for their lives in such aspects as completion of their study and getting education, keeping their jobs, establishing and keeping up their family relations.
- A.V. Kurmanayevskiy, I.N. Abdyusheva, I.V. Anoshkin were not subjected to any discrimination in the field of health protection and obtaining medical aid. The applicants were not subjected to discrimination in connection with their health state in violation of Article 14 of the Convention, taken in conjunction with Article 8 of the Convention, in connection with a ban on drug addiction "treatment" using methadone and buprenorphine.

In view of the foregoing, representing the interests of the Russian Federation in accordance with the Regulation on the Representative of the Russian Federation at the European Court of Human Rights approved by Decree of the President of the Russian Federation of 29 March 1998 no. 310,

I SUBMIT:

that the application of A.V. Kurmanayevskiy alleging violation of his rights guaranteed by Articles 8 and 14 of the Convention is manifestly ill-founded within the meaning of Article 35 §§ 1, 3 (a) and 4 of the Convention;

that the applications of I.N. Abdyusheva, I.V. Anoshkin alleging violation of their rights guaranteed by Articles 8 and 14 of the Convention are manifestly ill-founded within the meaning of Article 35 §§ 3 (a) and 4 of the Convention.

I ASK:

to dismiss the application of A.V. Kurmanayevskiy alleging violation of his rights guaranteed by Articles 8 and 14 of the Convention as manifestly ill-

founded according to Article 35 §§ 1, 3 (a) and 4 of the Convention;

to dismiss the applications of I.N. Abdyusheva, I.V. Anoshkin alleging violation of their rights guaranteed by Articles 8 and 14 of the Convention as manifestly ill-founded according to Article 35 §§ 3 (a) and 4 of the Convention.

Attachment: on 382 pages.

G. Matyushkin
<signature>