REPORT on the HEPATITIS C (HCV) and its TREATMENT SITUATION in LATVIA

Introduction

The Society «Association HIV.LV», founded in 2006[1], until now has been reviewing hepatitis C problems only in the context of HIV co- infection, and since activities in the field of hepatitis C are not foreseen by its Statutes[2], actually has not been separately engaged in HCV prevalence, HCV treatment accessibility research or advocacy in its field. Only one non- governmental organisation (NGO), the „Hepatitis Society"[3] is working in Latvia (since 2003): it unites HCV patients, supports them psychologically and legally, defends HCV patients' rights, advocates for treatment accessibility and informs general population on hepatitis C. However, the statutory aim of the „Hepatitis Society" is to work with country's general population, while work with groups most at risk of getting infected with HIV and HCV (including HCV antibody routine testing) is being performed within the limits of finances by harm reduction programmes and HIV/AIDS NGOs. This has ultimately initiated the Society „Association HIV.LV" in 2010-2011 to substantially investigate the situation with hepatitis C in Latvia, especially accentuating the groups of HIV- infected people, convicted ones, intravenous drug (ID) users and women engaged in commercial sex.

The given report comes as the result of the project „Hepatitis C: Hesitation is Dangerous!", accomplished in 2011 by the Society „Association HIV.LV", with the financial support of the *Foundation „Open Society Institute*". The report should not be viewed as a professional research; its aims were to collect the factual data, to identify problems and to search for solving suggestions, and also to propose eventual advocacy directions. The project had also not envisaged an analysis of patent rights, rights on intellectual property, and international obligations in this field undertaken by the Latvia State.

The main conclusions of the Report:

- ✓ The current system of financial limits on laboratory examinations is not motivating general practitioners to propose routine tests of hepatitis C to their patients, thus the infected ones are not suspecting their health status.
- ✓ Patients ready to start hepatitis C treatment are not aware of how much they will have to pay extra for the medication.
- ✓ There is no register of hepatitis C patients in Latvia, which results in non- existence of tools to objectively measure treatment effectiveness or adherence to it.
- ✓ The main problems in hepatitis C treatment (in decreasing order) are: insufficient financing from the State; inadequate management of treatment side effects; non- adherence to treatment.
- ✓ In the course of 7 years of interdepartmental consultations, the conception of medical care for incarcerated persons is still not adopted; prison medicine is not integrated into public health care, which actually prohibits incarcerated and convicted persons their right of adequate healthy well- being.
- ✓ The work in the field of primary and secondary hepatitis C prevention among the general population done by the State and non- State institutions is not systematic and totally insufficient.
- ✓ In prisons ID use harm reduction programmes are not available, and hepatitis C routine tests, covered by the State, are not provided, which leads to an intravenous spread of infection without knowledge.
- ✓ ID use among women is strongly interrelated to commercial sex, and hepatitis C prevalence is close to 50%.
- ✓ The tested persons are fairly conscious about themselves, and aware of drug use as their own problem and that of the society as a whole.

1 Biedrības "Apvienība HIV.LV" reģistrācijas apliecība http://www.apvienibahiv.lv/organizacijas-apraksts/aplieciba
2 Biedrības "Apvienība HIV.LV" statūti http://www.apvienibahiv.lv/organizacijas-apraksts/statuti
3 Hepatīta biedrība http://www.hepatits.lv/lv/pacientiem/hepatita-biedriba

- ✓ A good knowledge characteristic among the tested persons about the risks without practical application of this knowledge does not prevent them from infecting with hepatitis C.
- ✓ Contrary to expectations, the increase of HIV/HCV co- infections is not too topical for Latvia, compared to separate increase in HIV or hepatitis C infection cases.
- ✓ There is no NGO representative in the Consultative Council on Pharmacology (MH), who could directly defend the interests of HIV or hepatitis C infected persons.

Some recommendations *(a full list of recommendations see at the end of this Report)*

- ➢ The MH should maintain the 75% State compensation of out- patient hepatitis C treatments as from January 1, 2012, and consider a compensation of up to 90% starting from July 1, 2012.
- ➢ The Health Economics Centre should include the innovative hepatitis C protease inhibitors into the State compensation list „C" as from March 1, 2012 for treating 10 chronic hepatitis C patients providing that pharmacological companies producing these medications are covering 30% of their basic price, plus are fully covering treatment for 10 more patients.
- ➢ The Health Economics Centre should elaborate and confirm increased treatment adherence medical technology for all the patient groups, and start it from July 1, 2012.
- ➢ The Ministry of Health (MH), the Ministry of Justice (MJ) and the Ministry of Finances (MF) should come to an agreement on the integration of penitentiary medicine into the general health care system, and implement this integration as from January 1, 2013.

1. Methodology of the Report

- An analysis of the available statistical data, publications and the results of previous projects of the Society.
- Voluntary consulting and testing (VCT) of the convicted persons (imprisoned persons under judicial examination were not tested) for hepatitis C and HIV antibodies in places of detention (PD), followed by questionnaires, especially elaborated for the given Project to be filled in by persons with positive HCV antibody tests.
- VCT of women engaged in commercial sex for hepatitis C antibodies, followed by questionnaires, especially elaborated for the given Project to be filled in by persons with positive HCV antibody tests.
- Interviewing experts (doctors, officials, pharmaceutical and NGO representatives) by means of a handbook especially elaborated for the given Project.
- Analysis of the available statistical data from harm reduction programmes on VCT for hepatitis C antibodies.
- Identification of problems and elaborating recommendations.

2. *General information*

2.1. HCV prevalence in Latvia

In 2010 there were 61 (2,71 per 100000 of population) cases of newly diagnosed acute HCV and 1051 (46,74) chronic HCV.

From 2005 to 2009 the medium was 103,2 of acute and 1314 of chronic HCV cases per year.[4] In the first half of 2011 there were 29 cases of newly diagnosed acute HCV and 575 chronic HCV.[5]

In 2008, the Infectology Centre of Latvia (LIC) has done an epidemiological investigation to estimate hepatitis C prevalence in Latvia. The investigation has shown that from 55200 persons contiguous to hepatitis C, 39000 (1,7% of general population) have acquired it, but only 17000 knew that they were infected.[6] Since then there have been no newer investigations.

4 Latvijas Infektoloģijas centrs http://lic.gov.lv/docs/268/2011/Epid.bileteni/Inf_sl_01-12_2010.pdf
5 Latvijas Infektoloģijas centrs http://lic.gov.lv/docs/268/2011/Epid.bileteni/Infekcijas_slimibas_06_11.pdf
6 http://lic.gov.lv/index.php?p=780&pp=8952&lang=258 , http://zinas.nra.lv/maja/veseligs-dzivesveids/53027-latvija-c-hepatita-briesmas.htm , http://www.novonews.lv/index.php?mode=news&id=119051

May 31, 2011 LIC data shows that from 3409 registered HIV infected persons 1980 patients (58,1%) are co- infected with HCV.[7]

The Latvian Prison Administration in its yearly Report, 2010 gives the following statistics of infectious diseases (based on symptomatic examinations or existing documented anamnesis in penitentiary system): cases of HIV infection – 657, AIDS - 120, acute HCV - 5, chronic HCV - 405. There are 1265 ID users in PD, and 1789[8] cases of registered drug use.

There is no other statistical data on other population groups at our disposal.

From 2007 to 2010, a cohort investigation on the tendencies among drug users was held in Latvia.[9] In its course, 53 to 66% of ID users indicated themselves as HCV- infected ones.

2.2. Testing and prevention

In the field of prevention, a normative Act „Practical Guidelines on hepatitis B, hepatitis C and HIV Infections' Prevention in Medical Establishments", 2008[10], is in force. An overall task to provide a specific prevention of infectious diseases and to instruct specialists is set in the functions of the State Agency „The Infectology Centre of Latvia".[11]

Upon a positive HIV diagnosis, an HCV test is included in the obligatory list. HCV tests for donors' blood are a compulsory prerequisite.

Based on the amount of patients registered at a general practitioner, a system of financial limits on laboratory tests („money follows the patient")[12] is set as of January 1, 2011. As a result, doctors are forced to follow these limits, and are not prescribing HIV and hepatitis routine tests.

Patient's payment for a visit to a general practitioner is 1 Latvian Lat (2 USD), for a veins blood test:
1 LVL, for a visit to a specialist: 3 LVL (6 USD).[13]

Upon availability of resources, harm reduction programmes and NGOs provide routine tests (offered to everybody) for HCV antibodies. They are also providing the most of primary HCV prevention work.

2.3. Diagnostics and treatment

National „Recommendations on Rational Pharmacotherapy of hepatitis C in the Frame of Compensatory System", 2005 [14] are in place in Latvia. A full algorithm of diagnostics, prescriptions and treatment monitoring is foreseen in it. Laboratory tests are to be implemented at the same laboratory and by the same methods.

During diagnostics the following tests are provided: ALAT activity, HCV RNS antibody existence, viral load, virus genotype, as well biopsy sample's investigation – indicators of liver inflammation is estimated, and fibrosis level is determined. Treatment, including choice and dosage of medications, is prescribed only by a consultation of hepatologists – infectionists. The consultation also has to estimate the forecasted patients' adherence to treatment, especially in cases of drug use or chronic alcoholism.

Treatment for drug users is prescribed only in cases of stopped drug use and undoubted wish to be treated. The decision to start treatment is obligatorily agreed upon by patients' psychiatrist or narcologist.

Complementary prerequisites to prescribe treatment are: limiting alcohol consumption,

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7 Latvijas Infektoloģijas centrs http://www.apvienibahiv.lv/docs/729/2011-dazadi/hiv_atsk_052011.pdf
8 Ieslodzījuma Vietu pārvalde http://www.ievp.gov.lv/index.php?option=com_content&view=article&id=72&Itemid=75&lang=lv
9 Kohortas pētījums par narkotiku lietošanas tendencēm un paradumiem Latvijā http://vec.gov.lv/uploads/files/4e0f33326c3b0.pdf
10 Latvijas Infektoloģijas centrs http://lic.gov.lv/docs/268/PublLidz-2009/01vadlinijas_vhb_vhc_hiv_profilakse_arstn_iest.pdf
11 Valsts aģentūras "Latvijas Infektoloģijas centrs" funkcijas un uzdevumi http://www.lic.gov.lv/index.php?p=773&pp=233&lang=258
12 Veselības Norēķinu centrs http://www.vnc.gov.lv/lat/ligumpartneriem/budzetaresursi/index.php?doc=2123
13 Veselības Norēķinu centrs http://www.vnc.gov.lv/lat/veseliba/Pacientuiemaksas/
14 Veselības Ekonomikas centrs http://vec.gov.lv/uploads/files/4d08c09c5b481.pdf

decreasing body mass (in cases if BMI> 25 kg/m2), vaccination against hepatitis A and hepatitis B, use of safe contraceptives.

Treatment of I or IV genotypes is prescribed for 48 weeks, for others – 24 weeks. In cases of genotypes I or IV, after 12 weeks of treatment initiation, quantity of HCV RNS is measured: treatment is being prolonged provided a minimum 100 fold decrease is reached, if not – it is stopped. In cases of other genotypes, a qualitative HCV RNS test is being implemented 24 weeks after the treatment initiation.

By general practitioner's or infectionist's assignment HCV diagnostics and examinations prior to and during the treatment of free patients are covered by the State. Patients without an assignment or persons with temporary residence permits are paying a full price. The following are some laboratory diagnostics' costs as of August, 2011 (State[15] /private[16]laboratory) in Latvian Lats (and US Dollars): IFA antibody test 4,15 / 4,40 (8,50 / 9); Western Blot 27,93 / 35,00 (51 / 71,7); Qualitative PCR test 36,82 / 40,15 (75,45 / 82,27); PCR viral load 77,07 / 91,65 (157,93 / 187,8); Genotyping with subtypes 115,35 /128,65 (236,37 / 263,63); Genotyping without subtypes: 68,92 / - (141,22 / -).

Prices in laboratories, financed by the MH budget are gradually decreasing since 2009. Previously, the situation was contrary – the prices at private laboratories were lower.

The minimal cost of complex investigations prior to treatment prescription (incl. overall analysis, biochemistry, puncture, sonography, etc.) is 278 LVL (570 USD).

Treatment of chronic hepatitis C is compensated by the State since January, 2006. The level of compensation until February 28, 2009 was 75%, afterwards reduced to 50% due to health budget decrease during the economical crisis. To compensate medications the State spent (LVL/USD[17]): 1,15 / 2,35 million in 2006; 2,69 / 5,51 - in 2007; 2,66 / 5,45 - in 2008 and 1,33 / 2,72 - in 2009.[18]

With a 50% State compensation in 2010, 862 chronic HCV patients received pegylated Interferon, 3 – linear Interferon, 47 acute HCV patients received lineal Interferon, and the State expenditure was 2 million LVL[19] (4,1 million USD).

After the decrease in the State compensation, the agencies of pegylated Interferons producers – pharmaceutical companies – covered ¼ of their price in pharmacies to patients. Later, by the Regulation № 899 of the Cabinet this practice of deductions and grants by a third party for acquisition of State- compensated medications was forbidden as distorting competition in pharmacology sector and as causing inequality among patients.

Besides, from October 1, 2009 to December 31, 2011 patients (incl. HCV patients) who are considered by social departments of their residence as indigent or poor, are not additionally paying for State- compensated medications: their part is compensated by the World Bank credit's resources of Social protection Strategy which was granted in the frame of economic aid to Latvia in the context of economical crisis.[20]

With the enforcement of the new wording of the Regulations № 899, from January, 2011 an absurd situation started taking place when the poor patients received HCV medication free of charge but patients with a minutely higher income were forced to pay for their medication a sum, totalling almost double monthly subsistence minimum which was 171,41 LVL (351,25 USD)[21], while the medium wage (after tax reductions) in 2010 was 316 LVL (647 USD).[22] Therefore, temporary from March 1 to December 31, 2011, the 75% compensation level was restored. Here is the dynamics in numbers of unique HCV patients, receiving treatment in 2011: January – 737

15 Ministru kabineta noteikumi Nr.528 "Noteikumi par valsts aģentūras "Latvijas infektoloģijas centrs" publisko pakalpojumu cenrādi" http://www.likumi.lv/doc.php?id=113052&from=off

16 Gulbja laboratorija http://194.19.248.24:1973/csp/ec/ec.pricelist.cls

17 1 USD = 0,4880 LVL 19.08.2011 http://www.bank.lv/

18 Veselības Norēķinu centrs http://www.vnc.gov.lv/lat/ligumpartneriem/budzetaresursi/index.php?doc=391

19 Veselības Norēķinu centrs http://www.vnc.gov.lv/files/VNC_kompensejamo_zalu_apmaksa_razotaji_2010.xls

20 Ministru kabineta noteikumi Nr.899 "Ambulatorajai ārstēšanai paredzēto zāļu un medicīnisko ierīču iegādes izdevumu kompensācijas kārtība" http://www.likumi.lv/doc.php?id=147522&from=off

21 Iztikas minimuma patēriņa grozs vienam iedzīvotājam http://www.csb.gov.lv/statistikas-temas/iedzivotaju-ienemumi-galvenie-raditaji-30268.html

22 Iedzīvotāju naudas ieņēmumi http://www.csb.gov.lv/iedzivotaju-naudas-ienemumi-videji-menesi-latos

patients with chronic HCV on pegylated Interferon + 8 patients with acute HCV on linear Interferon; February – 353 + 12 patients; March – 427 + 10; April – 385 +12; May – 408 + 6; June – 407 + 11 + 1 patient with chronic HCV on linear Interferon.[23]

In the frame of compensation system the price (LVL/USD) of medications (incl. VAT) for HCV treatment since July, 2011 is: Roferon- A: 14,48 LVL / 29,67 USD for 1 injection; Realdiron: 75,04 LVL / 153,77 USD for 5 injections; Ribavirin (200mg): 13,33 LVL / 27,32 USD for 20 capsules; Pegasys (0,135 mg): 127,72 LVL / 261,72 USD for 1 injection; Pegasys (0,18 mg) + Copegus (200 mg): 589,02 LVL / 1207 USD for 4 weeks; Pegintron + Rebetol (200 mg) for 4 weeks in Peginterferon's dosage: 0,05 mg - 278,48 LVL / 570,65 USD; 0,08 mg – 445,55 LVL / 913 USD; 0,1 mg – 556,92 LVL / 1141,23 USD; 0,12 mg – 668,29 LVL / 1369,45 USD; 0,15 mg – 835,35 LVL / 1711,78 USD.[24]

Thus, the cost of treatment with pegylated Interferon Pegasys is: 3534 LVL / 7242 USD for 24 weeks, or 7068 LVL / 14484 USD for 48 weeks. The medium price of treatment with pegylated Interferon Pegintron is: 3341 LVL / 6847 USD for 24 weeks, or 6683 LVL / 13695 USD for 48 weeks.

Prices for medications are the third cheapest in the European Union, and not above their price in Lithuania or Estonia. The calculated financial request for covering the compensatory system's expenses of medications for in- patient HCV treatment in 2011 is estimated 1,8 million LVL/ 3,7 million USD, during 6 months the actual expenditure is 1,53 million LVL/ 3,13 million USD.[25]

The compensatory system's medication prices are being overlooked twice a year. The overview of compensatory system's operation and of medications' price formation during the economical crisis is given in *"Pharmaceutical policy and the effects of the economic crisis: Latvia"*[26] (basic information about compensatory system in Russian[27]).

2.4. Penitentiary system

Since July, 2009 in the Latvian penitentiary system by entering a prison, a person is tested only for HIV infection, tests being covered by the public healthcare resources. Other diagnostic examinations are performed, provided there are pronounced symptoms of illness or by patients' full payment.

Compared to the pre- crisis year 2008, in 2010 financing of medications, medical goods and diagnostic examinations has been decreased by 69,2%, and was 5,3 LVL/ year for out- patient medical care of one incarcerated person. Since 2009, reduction of PD staff is taking place as well, so, in 2011 it reached 19% (the reduction of medical staff: 59,4%.[28])

In 2011, series of interagency consultations on prison medicine's integration into the public health care have been held. In the PD only HIV infection's and tuberculosis treatment is covered from the public healthcare sources (Cabinet Regulations № 1046, paragraph 17.2)[29], so no other State- compensated medications (incl. those for treatment of hepatitis C) are available to incarcerated and convicted persons. This is the biggest problem for all the patient groups in PD (excluding HIV and TB). Diagnostics in cases of pronounced symptoms of illness is paid by penitentiary system under special permission.

From 2004 to 2006, MJ and MH elaborated the Conception of medical care for incarcerated persons; in 2006, a draft Conception was presented at a Cabinet meeting, and Minister of Health proposed to proceed with elaborating the versions of the Conception. In 2010, it was decided to stop this work. However, since elaboration of this Conception is foreseen by the confirmed

23 Veselības Norēķinu centrs http://www.vnc.gov.lv/files/VNC_komp_med_parskati_pieteiceji_01_06_2011.xls
24 Veselības Ekonomikas centrs http://vec.gov.lv/uploads/files/4e2fb409769ca.pdf
25 Veselības Norēķinu centrs http://www.vnc.gov.lv/lat/ligumpartneriem/budzetaresursi/index.php?doc=2125
26 Eurohealth, Volume 17, Number 1, 2011 http://www2.lse.ac.uk/LSEHealthAndSocialCare/LSEHealth/pdf/eurohealth/VOL17No1/Vol17No1.pdf
27 Veselības Ekonomikas centrs: Система компенсации приобретения лекарств http://vec.gov.lv/RU/spisok-kompensiruemyh-lekarstv
28 HIV/TB/STS izplatības ierobežošanas koordinācijas Komisija http://www.apvienibahiv.lv/docs/729/Komisiju_protokoli/cietumu_medicina.ppt
29 MK noteikumi Nr.1046 "Veselības aprūpes organizēšanas un finansēšanas kārtība" http://www.likumi.lv/doc.php?id=150766

Government's „Principles of Limiting the Prevalence and Control over Psycho- active Substances and Dependencies, 2011- 2017"[30] (paragraph #22), the interagency consultations in 2011 have been resumed.

3. Description of gathering instruments of quantitative data; quantitative data obtained in the course of Project implementation

3.1. Testing of convicted persons

In the frame of this Project, VCT for hepatitis C and HIV antibodies of convicted persons (persons incarcerated for the period of investigation were not tested) was implemented in the period of January – March, 2011[31]. From the planned 200, tested were 208 convicted persons; HCV antibodies were discovered in 109 cases, 92 of them were discovered for the first time in patients' lives. These convicted persons simultaneously were tested for HIV: HIV antibodies were discovered in 6 cases, 4 of them were discovered for the first time in patients' lives. HIV/ HCV co- infections were discovered in 5 cases. Testing was provided using capillary blood *Hexagon* Express- tests.

During the post- test consultation each patient received explanation about antibody tests and was handed a specially published bilingual (Russian/ Latvian) brochure „For those testing for Hepatitis C Antibodies".[32] Patients with first- ever discovered HIV antibodies were directed to the prison's Medical department to give blood sample for affirmative diagnostics (financed from resources of public healthcare), while patients with HCV antibodies were recommended affirmative diagnostics and were interviewed using a questionnaire[33], especially elaborated for the given project.

Testing was provided by a certified nurse and a peer consultant; the testing record's form[34] was filled out in duplicate: one – for internal records and statistics, the other – for the person tested. Client's identification was chosen by him /herself – surname, name or code – only three clients chose the code. The filled in testing records are being kept in a place inaccessible to outsiders. In accordance to the co- operation agreement with the Latvian Prison Administration, the selection of convicted persons for testing was the competence of the PD[35].

VCT in the given Project was a continuation of activities in the project „Co- operation and Health" (2010) with its 214 convicted persons tested for HCV and HIV antibodies in March – September[36]. 126 persons with HCV antibodies were then discovered, 90 of them had the diagnosis for the first time in their lives. The same convicted persons were simultaneously tested for HIV antibodies: antibodies were discovered in 13 persons, in 3 of them – for the first time. HIV/HCV co- infections: 10 cases.

Thus, in the course of the calendar year, 422 convicted persons were tested for HCV and HIV antibodies. This gave basis for obtaining fairly presentable results, since in 6 prisons 7,9% of the average weighted amount per 1 year (5330 convicted persons) got tested. 16 convicted persons, directed by prisons' administrations for testing arrived, but refused getting tested. In total, 235 (55,7% of tested persons) were discovered with HCV antibodies, 182 (77,4%) of them – for the first time. HIV antibodies were discovered in 19 (4,5% of tested persons), 7 (36,8%) of them — for the first time. There were 15 (3,6% of tested persons) with HIV/HCV co- infections.[37]

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30 Narkotisko un psihotropo vielu un to atkarības izplatības ierobežošanas un kontroles pamatnostādnes 2011.–2017.gadam http://polsis.mk.gov.lv/LoadAtt/file57284.doc , HIV/TB/STS izplatības ierobežošanas koordinācijas Komisija http://www.apvienibahiv.lv/docs/729/Komisiju_protokoli/cietumu_medicina.ppt

31 Testēšanas rezultātu ieslodzījuma vietās kopsavilkums http://www.apvienibahiv.lv/docs/729/projekti_2011/Testesanas_rezultati_cietumi.doc

32 "C HEPATĪTS: Brošūra cilvēkiem, kuri testējas uz C hepatīta antivielām" / "Гепатит С: брошюра тестирующимся на антитела к гепатиту С" http://www.apvienibahiv.lv/docs/729/projekti_2011/HCV_broshura_final.pdf

33 Aptaujas lapas ieslodzītajiem, kam konstatētas antivielas uz HCV http://www.apvienibahiv.lv/docs/729/projekti_2011/HCV_anketa_ieslodzitie.doc

34 Testēšanas pārskata veidlapa http://www.apvienibahiv.lv/docs/729/projekti_2010/atskaite_BKT_blanka.pdf

35 Vienošanās par sadarbību ar Ieslodzījuma vietu pārvaldi http://www.apvienibahiv.lv/docs/729/projekti_2011/vienoshanas_ar_IeVP.doc

36 Testēšanas pārskati pa cietumiem http://www.apvienibahiv.lv/docs/729/projekti_2010/Testu_izlietojums_final.doc

37 Testēšanas rezultātu ieslodzījuma vietās kopsavilkums http://www.apvienibahiv.lv/docs/729/projekti_2011/Testesanas_rezultati_cietumi.doc

High first- time exposure in PD of HCV antibodies in convicted persons, in combination with other factors in the PD - big concentration of ID users, big amount of registered cases of drug use and non- existence of harm reduction programmes in the system – may indicate on a high prevalence of new HCV infection cases during imprisonment.

Low first- time exposure of HIV antibodies in convicted persons in the course of our examinations is eventually conditioned by the fact that they may have been primarily tested during the „window" period upon entering PD, and because a repeated HIV test is not provided in PD unless there are clear symptoms indicating an eventual infection. Nevertheless, the risk of getting HIV, as well as HCV–infected during the imprisonment is very high because prisoners and convicted persons are more frequently using their right to officially refuse the test: 415 persons – in 20019, 763 persons – in 2010.[38]

Activities of the above mentioned Society's „Association HIV.LV" projects in PD were twice reviewed at the meetings of the Coordinative Commission of Limiting the Prevalence of HIV, TB and STD: in November 23, 20100 and March 16, 2011. The minutes of Commission's meetings and Society's presentations are published[39]. (This Commission is reviewing HCV problems only in the context of HIV, since there are no specialized HCV coordinative institutions).

3.2. Testing in women

In the frame of this Project from December, 2010 to March, 2011 voluntary testing for hepatitis C antibodies was provided for women, regularly or episodically engaged in commercial sex („street prostitution") in Riga and its surroundings. From the planned 100, tested were 120 women, 60 of which (50%) had HCV antibodies. Post- test consultation was analogous to that in prisons: the tested persons received the brochure, but women with HCV antibodies were interviewed using the questionnaire[40], especially elaborated for the Project. Testing and the interview was provided by nurses, the form of record was filled out in one copy for inner records and statistics, the tested women were identified only by a code. Women were not tested for HIV.

From June to September, 2011 an epidemiologic research *«Highly active prevention: scale up HIV/AIDS/STI prevention»* among women engaged in commercial sex is taking place. In its course tests for HIV, HCV and other infections are being provided, and 250 women are being interviewed.[41]

3.3. Testing of drug users

For the same period (December, 2010 – March, 2010), complementary data on tests for HIV and HCV antibodies in ID users are also obtained from harm reduction programmes in Riga.
From 174 persons tested (107 women and 67 men), HIV antibodies were discovered in 15 cases (8,6%; in 12 women (11,2%) and in 3 men (4,5%)); HCV antibodies were discovered in 104 cases (59,8%; in 52 women (48,6%) and in 52 men (77,6%)). 9 tested persons (5,2%) showed HIV/HCV co- infection.

3.4. Conclusions

Consequent on test results, ID use among women is very strongly intertwined with engagement in commercial sex, and hepatitis C prevalence is close to 50%.

Evidently, for Latvia the increase in HIV/HCV co- infection cases is not as topical as the separate increase of HIV or hepatitis C infection cases. The June 30, 2009 data of the Infectology Centre of Latvia (LIC) shows 1864 co- infection cases (62,1% from the registered and examined HIV- infected persons), on 31.12.2009 - 1888 (61,3%), on 31.12.2010 — 1947 (58,8%), on

38 HIV infekcijas, tuberkulozes un seksuālās transmisijas infekciju izplatības ierobežošanas koordinācijas komisijas sanāksmes protokols Nr. 14, Rīgā, 16.03.2011 http://www.apvienibahiv.lv/docs/729/Komisiju_protokoli/HIVKKprot_nr14_160311.doc

39 HIV infekcijas, tuberkulozes un seksuālās transmisijas infekciju izplatības ierobežošanas koordinācijas komisijas un ar to saistītu sēžu protokoli http://www.apvienibahiv.lv/starpnozaru-komisijas

40 Aptaujas lapa sievietēm (komercseksa pakalpojumu sniedzējām), kam konstatētas antivielas uz HCV http://www.apvienibahiv.lv/docs/729/projekti_2011/HCV_anketa_sievietes.doc

41 BORDERNETwork: Highly active prevention: scale up HIV/AIDS/STI prevention, diagnostic and therapy across sectors and borders in CEE and SEE. http://papardeszieds.lv/en/index.php?option=com_content&view=article&id=135:bordernetwork-highly-active-prevention-scale-up-hivaidssti-prevention-diagnostic-and-therapy-across-sectors-and-borders-in-cee-and-see&catid=11:projects&Itemid=40

31.05.2011 — 1980 (58,1%). Compared to the more than 2000 cases of newly discovered hepatitis C infections, the increase of 116 cases of co- infections in 2 years time seems insignificant. The same is shown by the data obtained during our project. Evidently, the peak of HIV/HCV co-infection exposure has already passed by.

4. **Review of the results from interviewing convicted persons and women engaged in commercial sex diagnosed with hepatitis C antibodies**

The questionnaires may conditionally be divided into 4 main groups:
general data of respondents;
the level of knowledge on hepatitis C, treatment and maintenance of normal functioning of liver;
the feasibility of affirmative diagnostics and covering the treatment financially;
the necessary measures of HCV prevention.
Data from the individual records of testing are also used in this Review.

109 convicted persons[42] and 60 women engaged in commercial sex (further on in this text: CSW)[43] got interviewed. (Results from questionnaires of each of the groups are published.)
The median age of respondents among convicted persons was: < 25 years - 23,8%, 25 to 35 years - 50,5%, 35 to 50 years - 24,8%; Among CSW: <25 years - 26,7%, 25 to 35 years - 61,7%, 35 to 50 years - 10%. Thus, the largest proportion of persons, eventually HCV- infected are young people up to 35 years old (79,3% from the total amount of respondents).

63,3% of convicted persons and 88,3% of CSW had the HCV test for the first time in their lives. This gives proof of insufficient accessibility of testing. There is a difference if a service "comes to a client" and is free of charge, or if it has to be sought and paid for.

Tests in the frame of harm reduction programmes previously were undergone by 1,8% of convicted persons and by 0% of CSW. There are two reasons for it: insufficiency in harm reduction programmes with testing availability, and episodic purchasing of HCV antibody express- tests for these programmes. Previously the test was undergone by 36,7% of convicted persons and by 11,7% of CSW, i. e., 27,8% of all respondents; besides, 53,2% of respondents were tested for the last time 5 years ago. The reason of the previous testing was: ID use among 27,5% of convicted persons and among 71,4% of CSW, i.e., among 34% of all the respondents, while testing reasoned on medical indications was implemented only among 40% of convicted persons.

In opinion of respondents the ways of getting HCV infection are: ID use – 73,4%, tattooing - 6,5%, unknown or unmentioned - 14,8%, and unsafe sex - 5,5%. This data shows fairly critical attitude towards themselves among respondents, acknowledging drug use as a problem; and at the same time – being precautious while tattooing. 5,5% of respondents consider having acquired HCV in prisons. 67% of convicted persons are ready to undergo affirmative diagnostics after the release, 7,3% are going to demand it from prison administration, 7,3% more are ready to pay for it in prison, and 14,7% are not going to take the tests. 81,7% of CSW are going to ask the general practitioner for affirmative test, 11,7% are ready to pay for it at private clinics, 5% shall stay aware they are not HCV carriers.

The answers on readiness to pay upon necessity for the treatment are interesting. Convicted persons ready to pay (LVL per month): 17,4% - over 100; 9,2% - 50 to 100; 12,8% - 10 to 50. CSW: 10% - 50 to 100, 31,7% - 10 to 50. But 43,2% of all respondents are not at all ready to pay for the treatment, i.e., the majority of respondents are well aware of non- existence of free medical services in the country, and are ready to pay a reasonable price according to their financial abilities.

77% of respondents are not complaining about the function of their liver, 21% have had complaints; 13,6% have taken medical advice (incl. in prisons) and 8,6% were not able to fulfil doctor's prescriptions because of lack of money.

Respondents' knowledge on risks of getting infected with HCV has been estimated as:

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42 Ieslodzīto, kuriem atrastas antivielas pret C hepatītu aptaujas apkopojums http://www.apvienibahiv.lv/docs/729/projekti_2011/Ieslodzito_aptauja_final.pdf

43 Sieviešu, kuras sniedz seksa pakalpojumus par maksu uz ielām un kam atrastas antivielas pret C hepatītu aptaujas apkopojums http://www.apvienibahiv.lv/docs/729/projekti_2011/KSD_Aptauja_HCV.pdf

very good and good - 66,3%; average - 20,1%. On HCV treatment: good - 31,3%, average - 40,2%. On the health of liver: good - 26,6%, average - 35,5%. We may conclude that sufficiently good level of respondents' knowledge without its practical application is not protecting from getting infected.

Personal responsibility in primary prevention. Personal responsibility as the most effective issue in not getting infected and not infecting others with HCV is regarded by 30,3% of convicted persons, while CSW have not even mentioned anything like it. 34,9% of respondents believe that drugs should not be used, and 18,9% are of the opinion that always having a personal syringe is sufficient. Only 3,5% of respondents would need more purposeful information on HCV. 22% of respondents are not interested in the given issue.

State responsibility in primary prevention. Respondents would like the following steps from the State in the primary HCV prevention: 34,9% - more money for different primary HCV prevention activities, 6,5% - enlarged availability of diagnostics, 5,9% - availability of sterile syringes in prisons, 16% - more special campaigns in mass media, 16% - a better harm reduction support from the State. 36% of respondents are not interested in the given issue.

Personal responsibility in secondary prevention. Respondents mentioned the following: 31,3% - healthy lifestyle (not using alcohol, drugs, observing diet, etc.), 17,2% - treating HCV, 3,6% - safe sex. 23% of respondents are not interested in the given issue.

State responsibility in secondary prevention. 49,7% - provision of free HCV treatment, 5,9% - increased financing the treatment, 13,6% - harm reduction programmes, 3% - HCV diagnostics free of charge once a year. 27% of respondents are not interested in the given issue.

Thus, at least 1/5 of respondents are not interested in HCV prevention, and they are not relating it to their private lives.

5. Analysis of experts' interviews

For interviewers special guidelines were elaborated on questions to be asked to experts and technicalities of interviews[44]. Since some of the experts flatly refused the publication of interviews or even mentioning their respective affiliation, the given rubric is rather a general conclusion of views expressed. All the experts were handed texts of their respective interviews, and they examined them. Experts, foreseen by the project proposal[45] were interviewed, excepting the WHO representative in Latvia who referred to lack of time and „enough materials on this issue on the WHO web- site". Instead, an interview not foreseen by this Project was taken from a general practitioner. Materials actual for 2011 on hepatitis C in Latvia referring to this Report could not be found on the WHO web- site. 8 experts altogether got interviewed.

Diagnostics. In opinion of the experts, Latvia with its HCV prevalence of 1,7% of general population corresponds with the global medium level of 1 – 2%. HCV is mainly being diagnosed in the process of compulsory check- ups (donors' blood, surgical interventions, pregnancies, HIV-infected patients). General practitioners are not providing routine HCV examinations, the reason being the introduced limits for laboratory tests. Some of the experts are declaring that general practitioners do not want or cannot identify hepatitis C, while LIC declares that they are sufficiently educated and are forwarding perceived HCV patients to LIC, and that cases of discovering HCV during the yearly prophylactic examinations covered by the public healthcare system are frequent, - the majority of patients with chronic or acute HCV are arriving in LIC by a general practitioner's assignment.

The MH is referring to the lack of finances for purposeful routine HCV examinations, and the main role in diagnosing lies upon patients' personal responsibility for his/her health and on general practitioners. Universal HCV screening throughout the country would hardly be effective and would be very expensive.

All the experts are of the opinion that HCV diagnostics (including affirmative diagnosis) and its

44 Vadlīnijas ekspertu intervētājiem http://www.apvienibahiv.lv/docs/729/projekti_2011/eksp_interv_vadlinijas.doc

45 Foundation Open Society Institute finansētais projekts "C hepatīts: vilcināšanās ir bīstama" ("Hepatitis C: hesitation is dangerous"). Projekta apraksts (angļu valodā) http://www.apvienibahiv.lv/docs/729/projekti_2011/LatviaAssociation_HIV.LV_Proposal2.doc

algorithm are of the highest quality. Diagnostics is provided free of charge, patient has to pay only the initial patients' payment for attending the physician.

All the experts are also of the opinion that affiliation to any certain social group is not at all influencing diagnostics. In the frame of harm reduction programmes, the State covers express- tests for drug users, CSW, their contact persons; however, there is a lack of these programmes, and responsibility on developing them and their functioning lies upon the wish for them of local authorities, and not the State.

Epidemiological services are actively searching patients who during check- ups were diagnosed as HCV infected, however, introduction of adequate epidemiologic investigation and control (e.g., seeking contact persons) in a democratic country is problematic: no one may be forced to get tested.

Treatment and prevention. While treatment of infectious diseases in Latvia is free of charge, in cases of hepatitis B and C an out- patient has to pay a certain percentage of medications' cost, which amounts to a considerable sum. As for the present, the poor and indigent patients (in 2010 there were 300 of such patients) are exempt from any payment. Those with a higher income are facing problems. A small amount of patients are getting help from local authorities.

The country's Constitution guarantees the minimum medical aid[46] to each inhabitant. Even the General Comment № 14 (2000) of the UNO on the right to the highest attainable standard of health[47] is not foreseeing the States' obligation to guarantee all the medical care for free. The MH is not aware of the level of medications' compensation in 2012, since it will depend upon the public health care budget to be ratified by the Parliament earliest in December, 2011. An elaborated conception of compensatory system's development foreseeing a considerable increase in the budget (32 million Lats) with inclusion of innovative medications should start operating in 2012; nevertheless, the MH already now considers it as unrealistic.

The quality of HCV treatment is regarded by experts as from „patching with Interferons" to „high". In average, the treatment course lasts from 6 to 12 months, however, patients' adherence to it is low: the majority of experts believe that only 1/3 of patients are completing the treatment. Patients' organisation considers that it is completed by maximum 5- 10%. According to the data of LIC, the viral output in the course of treatment is close to 100%, other experts are estimating it 80%; yet, with the time being, 40% of patients that have completed the course are getting tested with HCV in their blood again.

Paradoxically, there is no HCV patients' register in Latvia; nor unbiased, systematized data of the economical effectiveness of treatment; not even statistics on patients having started/ interrupted/ successfully completed the treatment. There is only precise data on the amount of unique patients who have bought medications, on the amount of medications sold, and on the sum of State compensation for them.

A part of the experts are estimating the side effects' management as unsatisfactory. In cases of threat to the health, patients get free aid at hospitals, with a patients' daily payment 5 LVL in LIC or 9,5 LVL in multi- profile hospitals. In ambulatory conditions, patients' compensation (50%) is foreseen only for antidepressants, however, they are exclusively prescribed by psychiatrists, and many patients are not ready to refer to them. Free psychological support is provided only by the LIC psychotherapist and by a sole hepatitis C patients' NGO.[48]

All the experts are of the same opinion that prices for compensation medications are very high, however the State follows their being the third cheapest in the EU, and not higher than in Lithuania or Estonia. To lower the existing basic (VAT excluded) prices for 5 to 10%, a new scheme of price formation is now being reviewed (to fix the price in Latvia as an arithmetic median of the three lowest prices in the EU).

While pharmacological companies are in the process of preparations, there are still no applications from their side for the inclusion of innovative HCV protease inhibitors into the list of

46 Latvijas Republikas Satversme, 111. pants http://www.saeima.lv/lv/likumdosana/satversme

47 General Comment No. 14 (2000) "The right to the highest attainable standard of health" (article 12 of the International Covenant on Economic, Social and Cultural Rights) http://www.apvienibahiv.lv/docs/729/projekti_2011/CESCR_General_Comment_14_1.zip

48 Hepatīta biedrība www.hepatits.lv

compensation medications.

All the experts are of the opinion that in hospitals there is enough of beds for treating HCV patients. Financing for in- patient treatment is also sufficient.

All the experts are totally critical on the availability of HCV diagnostics and treatment in PD, and are regarding this situation as inappropriate.

The first liver transplantation in Latvia was successfully implemented in 2010 (for a scientific research of the hospital and of its own budget). The State is not ready to pay for a liver transplantation to grown- ups (the operation in children is paid without delay). LIC affirms that the need for an immediate liver transplantation in grown- ups is minimum 20 operations per year. The total amount of necessary transplantations in May, 2011 was around 100.

HCV prevention is considered by experts as insufficient, „invisible", „in fact, non- existent". They stressed that general practitioners and pharmacies are practically not engaged in prevention.

Non- governmental organisations. Majority of experts are considering the advocating efforts for the interests of HCV patients as „insufficient", „poor", or even „non- existent". Experts are unanimous that NGOs working with HCV patients are „a few" or „insufficiently recognizable". A shortage of active advocacy leaders is being stressed. MH, in its turn, considers the necessity of active NGOs, since they have real powers predicted by the democracy to influence the situation, and that the protection of interests of HCV patients exists. At the same time, the MH „would not like more active organisations", since NGOs are mainly sending petitions for increased budget instead of giving concrete constructive suggestions. All the experts are unanimous that NGOs should be engaged in prevention, public information and patient support. At the same time, a part of experts are not fully aware of the difference between "protection of interests" and "advocacy", and have no comments on advocacy as such.

The next joint Project of the Society and the Latvian Prison Administration envisaging education of prisoners and convicted persons on HIV/ HCV/ TB and their testing for HIV and HCV antibodies is planned for 2014 when a drug- free prison, financed from the European funds, should be developed.

Although hepatitis patients' NGO willingly agreed for an experts' interview, it was not too enthusiastic about an eventual co- operation with HIV/AIDS NGOs.

6. Recommendations

- The MH should maintain the 75% level of State- compensated hepatitis C medications for in- patients as of January 1, 2012; simultaneously considering a higher compensatory level of up to 90% as of July 1, 2012.
- In order to give the Health Economics Centre the right (in case of over- draft during the first half- year of compensatory medicines from the list „B") to temporarily lower the basic price of medications from the list „B" for 15% during the period of September 1 to December 31, the MH should draft modifications to the Cabinet Regulations № 899.
- The MH should draft modifications to the Cabinet Regulations № 899, with a 15% lowering for the prices of brand medications patented over 10 years ago and not having generics.
- The LIC and the Health Economics Centre should create hepatitis C patients' register and start its operation as from January 1, 2012.
- The Health Economics Centre should elaborate and confirm a medical technology of increased treatment adherence of all patient groups, and start implementing it as of July 1, 2012.
- The Health Economics Centre should include the innovative HCV protease inhibitors in the list „C" of State- compensated medications as of March1, 2012 for treating 10 chronic HCV patients under a condition that 30% of the basic price of medications are covered by pharmaceutical companies producing these medicines, plus fully paying for treatment of 10 more patients.
- The LIC should elaborate and register new and substantial Clinical Guidelines for diagnostics and etiotropic treatment of hepatitis C (analogous to the Guidelines on hepatitis

B[49], registered in 2011) including treatment with new innovative medications by July 1, 2013.

- The LIC should provide prisons with HIV and hepatitis C antibody express- tests out of harm reduction resources in amount of minimum 1500 of each test.
- NGOs together with the State institutions should start creating a complex programme of social accompaniment of HIV and/ or hepatitis C patients, and implement it as of January 1, 2013.
- The MH should include into the Consultative Pharmaceutical Council an NGO representative who would directly protect the interests of HIV and hepatitis C infected persons as of January 1, 2012.
- NGOs should envisage complex measures in working with HIV/HCV co- infected persons into the 2012 application to the GFATM.
- MH, MJ and MF should reach an agreement on integration of penitentiary medicine into the public healthcare system, and implement the integration as from January 1, 2013.
- HIV/AIDS NGOs should actively fundraise to follow on with activities in HIV/ TB/ HCV primary and secondary prevention in PD, and for publishing respective patient- oriented literature.
- NGOs should actively advocate the implementation of above mentioned Recommendations by all the legal means.
- The Society „Association HIV.LV" in 2013 should prepare a report on the progress in the situation of hepatitis C and its treatment in Latvia.

49 Vīrushepatīta B diagnostikas un etiotropās ārstēšanas vadlīnijas http://vec.gov.lv/uploads/files/4dd4c8ea3b03c.pdf