# Report by the expert group on

# Road traffic safety and substitution treatment

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In view of the wide spread use of substitution therapy, as part of drug treatment programmes, the report examines state of present practices across Europe. It takes into account the effects of different substitution drugs on the ability to drive based on existing research. Furthermore the rehabilitation and integration implications of existing practise and regulations are explored.

In their work the experts took into account existing studies and research, in particular the Pompidou Group's previous work on drugs and road traffic, and the results of the DRUID Project.

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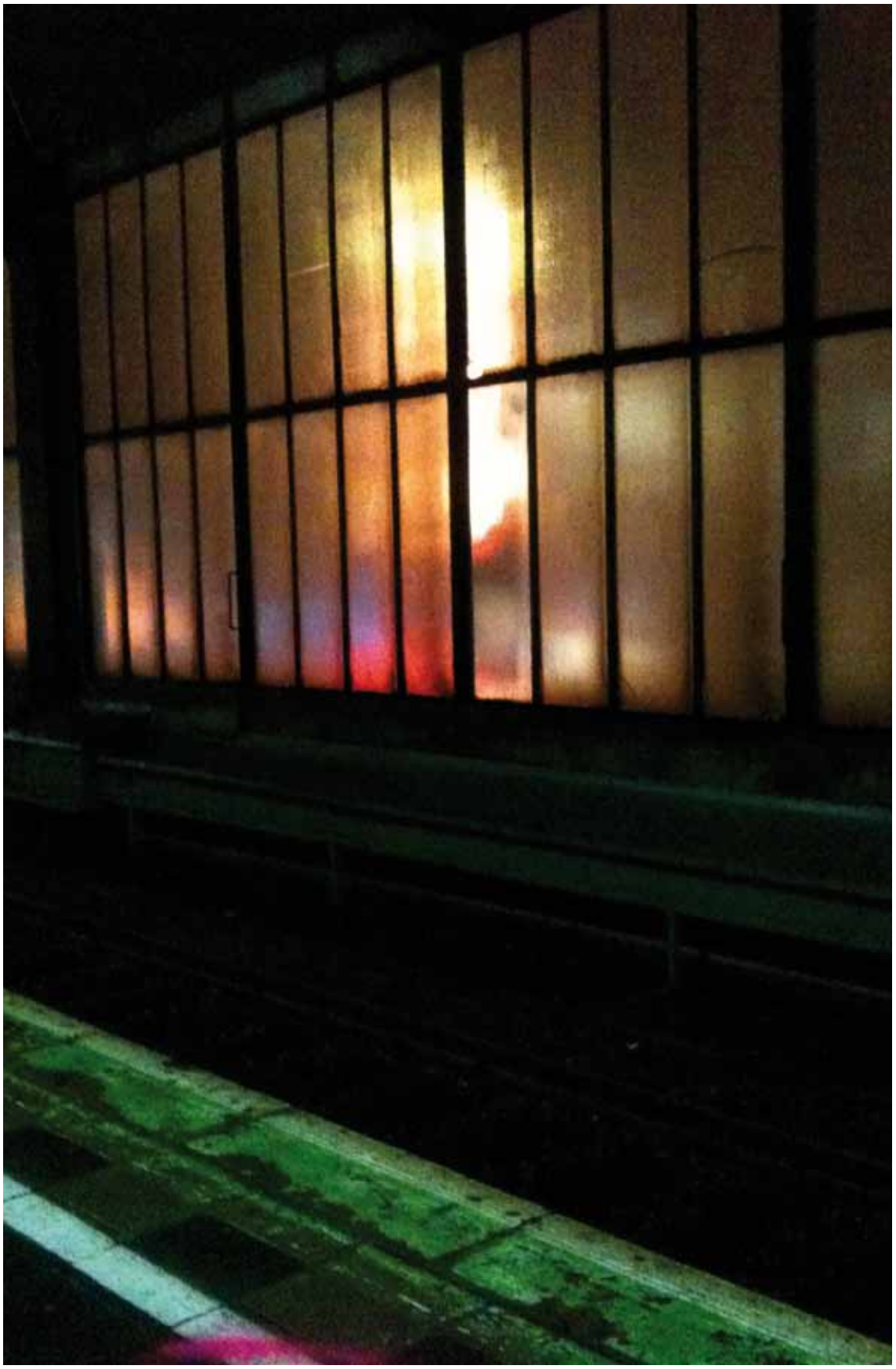

# 1 Overview of different approaches concerning substitution treatment and driving in Europe

## 1.1 Aim of the overview

Explore the state of present practice in Europe regarding substitution treatment and driving. The overview is performed as part of the work of the ad hoc advisory expert group on road traffic safety and substitution treatment.

## 1.2 Sources

Mainly feedback from questionnaires, see appendix 1-14, as well as a Council Directive on driving licenses from the European Union law [2]. Questionnaires were retrieved from Belgium (B), Croatia (HR), Cyprus (CY), Czech Republic (CZ), France (F), Greece (GR), Ireland (IRL), Italy (I), Lithuania (LT), Netherlands (NL), Norway (N), Slovakia (SK) and Sweden (S).

## 1.3 Summary of results

It is permitted to drive during substitution treatment in 9 out of 13 countries. In 5 of these countries the patient can choose to drive, usually after information from therapist. Norway is the only country where substitution treatment is mentioned in the law.

## 1.4 Table 1

**Summary of legal, medical and practical aspects of substitution treatment and driving in different European countries**

| Country | Substitution treatment mentioned in the law Y/N | Driving permitted during substitution treatment Y/N | Who decides whether patient can drive? | Scientific data |
|---|---|---|---|---|
| **B** | N | Y | Doctor | |
| **CY** | N | Y | Patient | |
| **CZ** | N | Y | Patient | 12 |
| **F** | Y | Y* | Officially: an accredited physician or a commission of 2 accredited physicians; in practice, very often, it is the physician who prescribes the therapy who gives advice to the patient. | 13 |
| **GR** | N | Y | Patient | |
| **HR** | N | Y | Patient | |
| **IRL** | N | Y | - | |
| **I** | N | Y/N | Local committees | 7, 9, 11 |
| **LT** | N | N | - | |
| **NL** | N | N | - | |
| **N** | Y | Y 4 | Physician | 6, 8, 10 |
| **SK** | N | N | - | |
| **S** | N | Y | Patient | 5 |

* With conditions

## 1.5 Regulations/guidelines within the EU

An EU Council Directive on driving licenses states “Driving licenses shall not be issued to, or renewed for, applicants or drivers who regularly use psychotropic substances, in whatever form, which can hamper the ability to drive safely where the quantities absorbed are such as to have an adverse effect on driving.” [2]

## 1.6 Issues that require special attention

- Impeding addicted persons entering a substitution therapy to drive can deter these patients to start such a therapy. (B)
- Lack of regulation for this specific area. (HR)
- Persons in therapy can test positive on drugs. (HR)
- Initiatives have to be undertaken in order for legislation to be adjusted and for procedures to be constructed and implemented. (GR)
- A particular issue, arising from the limited cooperation between complementary services and from gaps in legislation and in administrative instructions, is the following: in the case of specific crimes and violations of “the drug-related law”, the driving license of the offender is suspended. At the end of any such case, for the license to be given back, there is a special procedure, and a certification of “detoxification” is asked. The point is that there are not authorized services and structured procedures for the provision of such a document. Therefore, people get confused, tension is increasing and there are accumulating complaints and resentment. (GR)
- Lack of uniformity among Local Committees of the different cities. (I)
- The directives on substitution treatment and driving should be uniform throughout Europe. (I)
- Dosage of substitute drug has to be dealt with: it is useful to establish a limit for individuals requiring guide license. (I)
- Problematic to develop a selection instrument that detects all kind of drugs, without invading someone’s physical integrity. (NL)

## 1.7 Recommendations

- Recommendations to approaching substitution treatment and driving given in the feedback from the questionnaires:
- Based on available data driving under influence of substitution medicines does not pose substantial (if any) public health risk (CZ).
- It is both evidence based and clinically verified, that stabilized patients in substitution treatment are able to drive safely. Their right to possess and use a driving license has to be secured. Legitimization, which for the time being is missing, is essential (GR).
- One might assess in each case the individual controlled stabilization of the state of dependence and ability to drive, with close follow-up with a medical control. More strictly, it could be a precautionary measure, in the spirit of prevention of road accidents and traffic safety, not granting driving license during the use of substitute drugs, especially for methadone and buprenorphine, considering illegal drugs causing an impairment of driving ability (I).
- The literature in this field appears too limited to draw clear conclusions regarding maintenance use and driving. Evaluation of individual performance of maintained patients seems with the present knowledge to be the only useful procedure to approach the question of fitness for driving. (N).
- The Swedish system is based on restrictive regulation on substitution treatment and with a strict medical supervision. That is a guarantee that all patients are well informed and that they have no room for experiments on their own concerning prescriptions.

## 1.8 Table 2 Results Questionnaires

| COUNTRY | LEGAL ASPECTS | | | MEDICAL ASPECTS | PRACTICAL ASPECTS | |
|---|---|---|---|---|---|---|
| | Substitution treatment mentioned in the law Y/N | Driving permitted during substitution treatment Y/N | Legislation – Legal framework and regulation | Scientific data | Assessment procedures to accept driving | Conclusions and recommendations |
| B | N | Y | Punishment of alcohol intoxicated driving or analogues state due to the use of drugs or medicines.<br><br>Spit testing implemented.<br><br>Driving under influence of illegal drugs ---<br>- Fine.<br>- Interdiction to drive 5 days to 8 years.<br>- In case of recidivism: imprisonment. | | Doctor determine whether the substitution treatment impede driving capacity of the patient.<br><br>Morphine/ morphine-like medicines leaflets include warnings about conducting a vehicle --<br>- Strongly discourage to conduct a vehicle in a given latency.<br>- Warning of somnolence. | |
| CY | N | Y | Zero-tolerance for drugs (licit or illicit). | - | Clients receive brief advice of adverse effects related to driving under influence of prescribed drugs.<br><br>Only buprenorphine used in substitution treatment. | - |
| CZ | N | Y | - | [Ethanol and other psychoactive substances in fatal road traffic accidents in the Czech Republic in 2008]. [12]<br>- No positive result for opiates, n = 582<br>Annual report Drug situation 2009. | Substitution Treatment Standard: informed consent at the beginning of treatment on risks of activities under influence of substitution medicines, including car driving. | Based on available data driving under influence of substitution medicines does not pose substantial (if any) public health risk.<br><br>Number of substitution patients in Czech Republic: 4.000-5.000. |

| COUNTRY | LEGAL ASPECTS | | | MEDICAL ASPECTS | PRACTICAL ASPECTS | |
|---|---|---|---|---|---|---|
| | Substitution treatment mentioned in the law Y/N | Driving permitted during substitution treatment Y/N | Legislation – Legal framework and regulation | Scientific data | Assessment procedures to accept driving | Conclusions and recommendations |
| F | Y | Y | The law states (decree of 31/8/2010) that „driving is not compatible with the use of medicines which may impair driving skills or the driver‘s behaviour when the type of medicine or the dose taken entails à driving risk. When such medications are taken on a regular basis, an expert opinion is required, which takes into account the other health issues which affect driving capacity. In case of substitution therapy, this assessment must be carried out by a commission made up of 2 accredited practitioners. | Study on drugs consumed with medical prescription, including substitution treatment, and road accidents: CESIR-A [13]. | Therapists give individual advice.<br><br>Drugs are classified at three risk levels, this information is compulsory by law. Level 1 (yellow), very little influence. Level 2 (orange) in some cases impair driving ability; their consumption requires advice of healthcare professional. Level 3 (red) taken before driving is strongly discouraged.<br><br>Methadone and buprenorphine are classified level 2 and the box says “Be very careful, do not drive without a medical advice”. The risk when combining drugs in level 2 and 3 are considered to increase with increasing numbers of drugs. | |
| GR | N | Y | Zero tolerance legislation including all psychotropic substances.<br><br>Substitution treatment is not mentioned in the law.<br><br>Limits of blood concentrations exist only for alcohol. | Epidemiologic data exist for alcohol only. | No special assessment procedures to define if patients receiving substitution treatment are able to drive or not.<br><br>Services delivering substitution treatment are not responsible for issues of traffic safety and for measuring and controlling their patient’s ability to drive safe.<br><br>Patients are advised that as long as they conform to the medical rules and norms concerning their treatment their driving ability is not impaired and they can drive safely. Any deviation from treatment plan (missed doses, relapses, consumption of other drugs) is considered to possibly impair driving, and patient is asked to consult therapists. (Not standard procedures). | It is both evidence based and clinically verified, that stabilized patients in substitution treatment are able to drive safely. Their right to possess and use a driving license has to be secured. Legitimization, which for the time being is missing, is essential. |

| COUNTRY | LEGAL ASPECTS | | | MEDICAL ASPECTS | PRACTICAL ASPECTS | |
|---|---|---|---|---|---|---|
| | Substitution treatment mentioned in the law Y/N | Driving permitted during substitution treatment Y/N | Legislation – Legal framework and regulation | Scientific data | Assessment procedures to accept driving | Conclusions and recommendations |
| HR | N | Y | Zero-tolerance for illegal drugs.<br><br>Substitution drugs are not included among illegal drugs or medicines you should not use when driving<br>Driving under influence --<br>- license suspension period up to 6 months<br>- in case of recidivism: 12-24 months suspension<br>- fine<br>- Possibility of prison sentence up to 60 days. | - | The physicians who provide the therapy warn users about issues considering driving under the influence of these drugs.<br><br>Possibly assessments if a patient requests driver license for the first time or cause a traffic accident. | |
| IRL | N | - | It is illegal to drive or attempt to drive while under the influence of an intoxicant (alcohol or drugs or combination). | - | - | - |
| I | N | Y/N Depending on area in Italy, see appendix 9 | To obtain and maintain a driver's license absence of consumption and dependence to drugs is required.<br><br>Zero-tolerance of drugs is not officially regulated.<br><br>No law but guidelines for substitution treatment, but not specified for driving. | Scientific articles supporting inability to drive when using substitute drugs.<br>Ferrera et al. 2009 [9]<br>Bertol E, 2011 [7]<br><br>Subjects involved in car crashes in Florence, n = 554, 0.4 % positive for methadone. [11] | It is recommended to use caution when driving.<br><br>Ministerial recommendations for fitness to drive when in substitution treatment, but local committees act different.<br><br>Italy is working to standardize the protocols to check driving capability | One might assess in each case the individual controlled stabilization of the state of dependence and ability to drive, with close follow-up with a medical control. In addition, dosage of substitute drug has to be dealt with: it is useful to establish a limit for individuals requiring guide license.<br><br>More strictly, it could be a precautionary measure, in the spirit of prevention of road accidents and traffic safety, not granting driving license during the use of substitute drugs, especially for methadone and buprenorphine, considering illegal drugs causing an impairment of driving ability.<br><br>The directives on substitution treatment and driving should be uniform throughout Europe. |

| COUNTRY | LEGAL ASPECTS | | | MEDICAL ASPECTS | PRACTICAL ASPECTS | |
|---|---|---|---|---|---|---|
| | Substitution treatment mentioned in the law Y/N | Driving permitted during substitution treatment Y/N | Legislation – Legal framework and regulation | Scientific data | Assessment procedures to accept driving | Conclusions and recommendations |
| LT | N | N | Zero-tolerance legislation for driving under influence of drugs. Drug concentration does not impact penalty size or type, the driver is punished if drug is detected. | - | Patients are advised not to drive when in substitution treatment. | - |
| NL | N | N | In the Road traffic law it is stated that it is punishable to drive under the influence of a substance (drug, medicine, alcohol) that can have effect on the ability to drive. | There are some estimates on prevalence of driving under the influence of drugs, but not specified for methadone. | Patients are told not to drive.<br><br>In the Netherlands driving under the influence of methadone is no issue. | Number of substitution patients in the Netherlands: 12.000. |
| N | Y | Y | Legislative limits for driving under influence of 20 non-alcohol drugs, including methadone and buprenorphine, will be implemented in the law from 01.01.2012. [3]<br><br>Guidelines for driving licenses. [4] | An increased risk of road traffic accidents after prescriptions of methadone, SIR 2.4. [8]<br><br>No consistent improvement of neuropsychological tests in pain patients after switching from morphine to methadone, neither immediately or three months after switch. [10]<br><br>Methadone and impairment in apprehended drivers: methadone only psychoactive drug in 10 out of 635 drivers suspected of drugged driving. [6] | - Treatment under proper supervision and control with known physician<br>- Stable dose > 6 months<br>- No use of sedative drugs<br>- No use of illicit drugs ≥ one year. [4] | The literature in this field appears too limited to draw clear conclusions regarding maintenance use and driving. Evaluation of individual performance of maintained patients seems with the present knowledge to be the only useful procedure to approach the question of fitness for driving. |

| COUNTRY | LEGAL ASPECTS | | | MEDICAL ASPECTS | PRACTICAL ASPECTS | |
|---|---|---|---|---|---|---|
| | Substitution treatment mentioned in the law Y/N | Driving permitted during substitution treatment Y/N | Legislation – Legal framework and regulation | Scientific data | Assessment procedures to accept driving | Conclusions and recommendations |
| SK | N | N | Zero tolerance is basic principle for legal regulation. The driver must not take alcohol, addictive substances (substances which negatively influence human psychic or body control or perception) or medicines (that can decrease the ability to drive) before or during driving, including opiate agonists.<br><br>Toxicological examination is used after request of medical or control authority (including methadone) to identify drug and drug concentration. | Statistics are not differentiated for individual psychoactive substances. | Generally an alcohol or drug addiction (to be addicted to or regularly abuse addictive substances or medicaments) excludes the health ability to drive a car.<br><br>In accordance to the zero tolerance patients are told not to drive.<br><br>When the person was in the past drug addicted the health ability is possible to accept only on the base of specialized medical control and under the condition that he/she is regularly subordinated to medical control of drug addiction and results of medical control doesn't excluded health ability. | - |
| S | N | Y | Zero tolerance legislation of drugs in blood under or after driving a motor vehicle.<br><br>The law makes an exception from the zero tolerance for prescribed drugs (medical treatment). | The Transport Agency: In fatal accidents a total of 100 drivers out of 1462 had used narcotics (2005-2010). | The patient is responsible to decide whether he or she is able to drive but should always consult the responsible doctor. Advice not to drive in the beginning of the program. | Our system is based on a restrictive regulation on substitution treatment and with a strict medical supervision. That is a guarantee that all patients are well informed and that they have no room for experiments on their own concerning prescriptions. |

## 1.9 Conclusions

Based on the information in this report the following statements can be made:

- There seems to be a lack of evidence based protocols regarding substitution treatment and driving in most European countries.
- Many countries have zero-tolerance legislation for driving under the influence of drugs, but methadone or buprenorphine are not specified in the law. Substitution therapy is explicitly mentioned in the law in Norway and France. In France, a decree in 2010 states that if a patient has a substitution therapy, an assessment of the driving capacity must be carried out by a commission of 2 accredited practitioners.
- In most countries substitution patients are permitted to drive (9 out of 13 countries).
- Either the doctor/therapist or the patient, usually after information from therapist, determines whether the patient can drive. Information given to the patient is e.g. warnings of adverse effects related to driving under the prescribed drugs or more specific advices regarding consumption of other drugs or missed doses.

## 1.10 Reference list


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11. Mari F. Indian Journal of Forensic Medicine & Toxicology 2009;3:30-32.
12. Mravcík V, Zábranský T, Vorel F. [Ethanol and other psychoactive substances in fatal road traffic accidents in the Czech Republic in 2008]. Casopis lékaru ceských 2011;149(7):332-336.
13. Orriols L. Health-related factors and road safety : influence of medicine use (The CESIR-A study). 2010. Ref Type: Online Source

## 1.11 Appendix 1 Questionnaire

### A. RESPONDENT'S CONTACT DETAILS

| A.1.Full Name of Contact: | |
|---|---|
| A.2. Address:<br>City: | A.3. Telephone: |
| Postal Code: | A.4. Fax: |
| Country: | A.5. E-mail: |

### B. LEGAL ASPECTS

1. What is the relevant background information to describe the present situation in your country pertaining to the drugs and driving problems in general and to substitution treatment in particular? For example, introduction of "zero-tolerance" legislation, epidemiology of driving under influence of drugs in accidents, limits of blood concentration of drugs (either illicit or licit) which are acceptable or unacceptable for driving, etc.

2. Does the legislation in your country allow patients in substitution treatment to drive a car?

The substitution treatment is not mentioned in the law ☐

Yes, it is allowed to drive ☐
If yes, please explain how exactly it is regulated in the law?

No, it is not allowed to drive under substitution treatment ☐
If no, please explain how exactly it is regulated in the law?

### C. MEDICAL ASPECTS

1. In your country, are there any experimental studies to determine the nature of the impairment produced by drugs used in substitution treatment, specifically their impact on ability to drive?

No ☐

Yes ☐
If yes, please indicate the results or make a reference to relevant publication.

Don't know ☐

2. Are there statistics (e.g. annual numbers of injured or killed drivers who tested positive for methadone, etc.) for prevalence of driving under the influence of drugs used in substitution treatment?

No ☐

Yes ☐
If yes, please indicate the results or make a reference to relevant publication.

Don't know ☐

### D. PRACTICAL ASPECTS

1. Are there any assessment procedures to define if patient in substitution treatment is able to drive cars?

2. What advice is given to drug dependent patients about their treatment and driving fitness?

### E. ISSUES THAT REQUIRE SPECIAL ATTENTION IN APPLYING PRESENT POLICIES BASED ON NATIONAL EXPERIENCE.

In relation to the issue of substitution treatment and driving, what are the issues that cause problems in applying the present procedures or that have not been yet covered and need attention in adjusting existing legislation and/or procedures in your country?

### F. CONCLUSIONS AND RECOMMENDATIONS FROM NATIONAL EXPERIENCE.

Provide any advice based on the experience in your country with substitution treatment and road traffic safety.

### ADDITIONAL INFORMATION

If there is any additional information that is relevant to topic of the questionnaire, for example, legal texts or scientific research and publication, please list it here.

## 1.12 Appendix 2 Questionnaire Belgium

### B. LEGAL ASPECTS

*1. Regarding drug and driving in general, Belgium has recently implemented "spit testing".*

*Drivers under the influence of illicit drugs (THC; amphetamine; MDMA; MDEA; MBDB; morphine; cocaine or benzoylecgonine beyond a level determined by the Law) are liable to a fine of 1 100 to 11 000 Euros and to an interdiction to drive from 8 days to 5 years. In case of recidivism within three years, the offenders are liable to a penalty of imprisonment ranging from one month to two years. (Chapitre Vbis de la loi du 16/03/1968 relative à la police de la circulation routière).*

*Regarding substitution treatment is the law laconic. Art. 35 of the previously cited law punish alcohol intoxicated driving or analogous state due to the use of drugs or medicines.*

*2. The substitution treatment is not mentioned in the law* ☑

### C. MEDICAL ASPECTS

1. In your country, are there any experimental studies to determine the nature of the impairment produced by drugs used in substitution treatment, specifically their impact on ability to drive?

No ☑

2. Are there statistics (e.g. annual numbers of injured or killed drivers who tested positive for methadone, etc.) for prevalence of driving under the influence of drugs used in substitution treatment?

No ☑

### D. PRACTICAL ASPECTS

1. Are there any assessment procedures to define if patient in substitution treatment is able to drive cars?

No ☑

2. What advice (if any) is given to drug dependent patients about their treatment and driving fitness?

*Generally, medical doctors have an obligation to inform their patient if their physical or mental health isn't any more consistent with medical requirements (art. 46 AR 23 mars 1998). In turn, the patient must return his driving license to the competent authority within four working days from the day he became aware of the defect or condition.*

*It is up to the doctor to determine whether the substitution therapy impede the driving capacity of the patient.*

*All morphinic medicines leaflets include warnings about the conduct of a vehicle. They strongly discourage the conduct of vehicle in a given latency and warn about risk of somnolence.*

### E. ISSUES THAT REQUIRE SPECIAL ATTENTION IN APPLYING PRESENT POLICIES BASED ON NATIONAL EXPERIENCE.

*We need to pay particular attention to the fact that impeding addicted person entering a substitution therapy to drive can deter these people to start such a therapy. Too severe measures can thus have adverse consequences.*

## 1.13 Appendix 3 Questionnaire Croatia

### B. LEGAL ASPECTS

*1. The Law On The Safety In Road Traffic 67/2008, Art. 199, mentions driving under the influence of illegal substances as a non-criminal offence, with zero tolerance threshold. License suspension period can be up to 6 months (12-24 months if the offence is committed again in the next 24 months). There is also a fine (680 – 2039 Euro) and possibility of prison sentence of up to 60 days. As for substitution therapy, it is not mentioned explicitly anywhere in the text, and the fact that a person is in therapy does not present an obstacle for driving, since these drugs are not in the category of medicine you shouldn't drive while under the influence.*

*The substitution treatment is not mentioned in the law* ☑

### C. MEDICAL ASPECTS

1. In your country, are there any experimental studies to determine the nature of the impairment produced by drugs used in substitution treatment, specifically their impact on ability to drive?

No ☑

2. Are there statistics (e.g. annual numbers of injured or killed drivers who tested positive for methadone, etc.) for prevalence of driving under the influence of drugs used in substitution treatment?

No ☑

### D. PRACTICAL ASPECTS

1. Are there any assessment procedures to define if patient in substitution treatment is able to drive cars?

*Possibly only if a person requests a driver license for the first time, or if they caused a traffic accident while in therapy.*

2. What advice (if any) is given to drug dependent patients about their treatment and driving fitness?

*The physicians who provide the therapy warn the users about issues considering driving under the influence of these drugs.*

### E. ISSUES THAT REQUIRE SPECIAL ATTENTION IN APPLYING PRESENT POLICIES BASED ON NATIONAL EXPERIENCE.

In relation to the issue of substitution treatment and driving, what are the issues that cause problems in applying the present procedures or that have not been yet covered and need attention in adjusting existing legislation and/or procedures in your country?

*The main issue is the problem of lack of regulation for this specific area, as well as a possibility of a person on therapy testing positive on drugs, which can produce problems in practical aspects of not only police work, but also in medical practice.*

## 1.14 Appendix 4 Questionnaire Cyprus

### B. LEGAL ASPECTS

*1. As regards to driving under the influence of drugs (licit or illicit) the relevant legislation for Road Safety applies "zero tolerance" with the exception of alcohol, limit of 0.22mg blood concentration.*

*2. The substitution treatment is not mentioned in the law* ☑

### C. MEDICAL ASPECTS

1. In your country, are there any experimental studies to determine the nature of the impairment produced by drugs used in substitution treatment, specifically their impact on ability to drive?

*No* ☑

2. Are there statistics (e.g. annual numbers of injured or killed drivers who tested positive for methadone, etc.) for prevalence of driving under the influence of drugs used in substitution treatment?

Yes ☑
If yes, please indicate the results or make a reference to relevant publication (see table below).

## D. PRACTICAL ASPECTS

1. Are there any assessment procedures to define if patient in substitution treatment is able to drive cars?

*No* ☑

2. *What advice (if any) is given to drug dependent patients about their treatment and driving fitness? The clients receive brief advice as regards to adverse effects related to driving under the influence of prescribed drugs. However, methadone is not prescribed in Cyprus. Clients in substitution treatment are primarily prescribed subuxone (subutex & naloxone), and subutex among pregnant women undergoing substitution treatment.*

## E. ISSUES THAT REQUIRE SPECIAL ATTENTION IN APPLYING PRESENT POLICIES BASED ON NATIONAL EXPERIENCE.

In relation to the issue of substitution treatment and driving, what are the issues that cause problems in applying the present procedures or that have not been yet covered and need attention in adjusting existing legislation and/or procedures in your country?
This issue has not yet been given much attention, and legislation adjustments as regards to driving and substitution treatment have not been discussed. Currently, legislation adjustments have been introduced as regards to narcotest (drug testing), in order to minimise road traffic accidents related to drug use, pending for endorsement by the Parliament.

## F. CONCLUSIONS AND RECOMMENDATIONS FROM NATIONAL EXPERIENCE.

Provide any advice based on the experience in your country with substitution treatment and road traffic safety.
***N/A***

## ADDITIONAL INFORMATION

If there is any additional information that is relevant to topic of the questionnaire, for example, legal texts or scientific research and publication, please list it here.

***Section C Medical Aspects Q.2.***

### Deaths related to Drug Use 2004 – 2010

| Deaths | 2004 | 2005 | 2006 | 2007 | 2008 | 2009 | 2010 |
|---|---|---|---|---|---|---|---|
| Direct | 12 | 8 | 7 | 12 | 11 | 12 | 8 |
| Indirect | 5 | 6 | 10 | 10 | 2 | 3 | 4 |
| Total | 17 | 14 | 17 | 22 | 13 | 15 | 12 |

Total number of deaths 2004-2010 = 110

**Definitions of European Monitoring Centre (EMCDDA)**

**Direct deaths related to Drug Use:** Deaths due to overdose

**Indirect deaths related to Drug Use:** Deaths due to negative effects related to drug use apart from overdose (e.g. accidents, suicide etc.)

## 1.15 Appendix 5 Questionnaire Czech Republic

### B. LEGAL ASPECTS

2. *The substitution treatment is not mentioned in the law .*
*There is no legal provision against driving while taking substitution treatment medication. Substitution Treatment Standard stipulates that within Informal consent at the beginning of the substitution treatment; the client should have been informed about possible risks of some activities under influence of subst. medicine, such as car driving (Ministerstvo zdravotnictví ČR, 2008)*

*Ministerstvo zdravotnictví ČR (2008) Věstník MZ ČR částka 3/2008 - Standard substituční léčby .Praha: Ministerstvo zdravotnictví ČR.*
*Notes: http://www.mzcr.cz/Odbornik/dokumenty/vestnik_2035_1034_3.html [2010-08-12*

### C. MEDICAL ASPECTS

1. In your country, are there any experimental studies to determine the nature of the impairment produced by drugs used in substitution treatment, specifically their impact on ability to drive?

*No* ☑

2. Are there statistics (e.g. annual numbers of injured or killed drivers who tested positive for methadone, etc.) for prevalence of driving under the influence of drugs used in substitution treatment?

*Yes* ☑ *If yes, please indicate the results or make a reference to relevant publication.*

*Mravčík, V., Zábranský, T. and Vorel, F. (2010) Výskyt etanolu a dalších drog u smrtelných dopravních nehod v České republice v r. 2008. Čas Lék Čes 149 (7) 332-336.*

*Abstract: Ethanol and other psychoactive substances in fatal road traffic accidents in the Czech Republic in 2008*

*Goal: To map the recent prevalence of alcohol and other psychoactive substances in deceased victims of traffic accidents in the Czech Republic. Material and methods: The studied sample consisted of individuals autopsied in the departments of forensic medicine and forensic toxicology who died during traffic accidents in 2008 and were toxicologically tested for one or more of the following substances: ethanol, volatile substances, cannabis, opiates, stimulants, cocaine, benzodiazepines, and barbiturates. Case definition involved alcohol cases with blood alcohol concentration (BAC) 0,2 g/kg and higher; with cannabis, detections of active THC metabolites only were taken into account; from cases where volatile substances (solvents) were detected we included into the positive cases only those where substances were not produced post mortem or in some physiological or pathological statuses. Results: The sample consisted of 1,040 persons deceased in traffic accidents, of whom 582 (56.0%) were toxicologically*

*tested for one or more of the substances listed above. The sample has been divided into two subsamples – one of 778 (74.8%) active participants of road traffic accidents (pedestrians, bicyclists, and drivers) and other subsample consisting of 262 (25.4%) non-active participants. Ethanol was found in 38.3% of 381 tested and at least one of other psychoactive substances was found in 11.7% of 384 tested active participants –of those, stimulants (mostly methamphetamine) were found most frequently (6.5% of 337 tested), cannabis (5.9% of 203 tested) and benzodiazepines (3.9% of 363 tested active participants). Drivers were positive for ethanol in 29.2% cases, for one or more of other psychoactive substances except ethanol in 12.7% cases, most frequently for stimulants (9.2%) and cannabis (6.2%). Professional drivers were found negative for ethanol and other psychoactive substance except of one case of methamphetamine (6.7%). Conclusion: The study confirms high prevalence of alcohol and other psychoactive substances, especially stimulants (methamphetamine), cannabis and benzodiazepines, among deceased participants of road traffic accidents including drivers in the Czech Republic.*

*The article is written in Czech and besides others it is written there:*
*The results of the examination on opiates, cocaine and volatile substances are not mentioned – there was no positive result for opiates and cocaine, and only one for volatile substances (toluene) (one pedestrian positive for toluene out of 60 tested)*

## D. PRACTICAL ASPECTS

1. Are there any assessment procedures to define if patient in substitution treatment is able to drive cars?
*Not able to say – don't know*

2. What advice (if any) is given to drug dependent patients about their treatment and driving fitness?
*See above question 2 (the standards)...*

## F. CONCLUSIONS AND RECOMMENDATIONS FROM NATIONAL EXPERIENCE.

Provide any advice based on the experience in your country with substitution treatment and road traffic safety.
*Based on the data available, the driving under influence of substitution medicines does not pose substantial (if any) public health risk. Detection of substitution medicines in overdose deaths as well as death under influence of substances due to other causes that overdoses is rather negligible – even though the number of opiate users in substitution treatment in the Czech Republic is estimated as approx. 4000-5000 persons in recent years.*
*Driving under influence of more prevalent psychoactive medicines represents a greater public health concern – see the abstract above.*

## ADDITIONAL INFORMATION

If there is any additional information that is relevant to topic of the questionnaire, for example, legal texts or scientific research and publication, please list it here.

*See also the chapter on the detection of psychoactive substances in deceased victims of traffic accidents published annually in the Czech Annual report on the drug situation – www.focalpoint.cz.*

## 1.16 Appendix 6 Questionnaire France

### B. LEGAL ASPECTS

*The substitution treatment is not mentioned in the law .*
*The substitution therapy is mentioned in the law. The French law (decree of 31/8/2010 on application of the European Directive) states "driving is not compatible with the use of medicines which may impair driving skills or the driver's behaviour when the type of medicine or the dose taken entails à driving risk. When such medications are taken on a regular basis, an expert opinion is required, which takes into account the other health issues which affect driving capacity. In case of substitution therapy, this assessment must be carried out by a commission made up of 2 accredited practitioners.*

### C. MEDICAL ASPECTS

1. In your country, are there any experimental studies to determine the nature of the impairment produced by drugs used in substitution treatment, specifically their impact on ability to drive?

*1. A study named "CESIR-A" is currently conducted on drug consumed with medical prescription and road accidents including substitutive therapy.*

### D. PRACTICAL ASPECTS

2. *What advice (if any) is given to drug dependent patients about their treatment and driving fitness?*
*For September 2005, under the initiative of Afssaps, pictograms inform consumers about the level of risk posed by each product. Thus, drugs classified level 1 symbol yellow, very little influence on the conduct, the consequences depend on the susceptibility of each. Those at level 2, orange symbol, in some cases impair driving ability, their consumption therefore requires the advice of a healthcare professional. As for drugs with a risk level 3, red symbol, taken before their driving is strongly discouraged*

*The drug levels 2 and 3 represent the most risk on the road. Those are mostly anxiolytics, antidepressants, anticonvulsants, hypnotics and substitution treatments to combat drug addiction opiates. Indeed, these products often cause drowsiness, dizziness, blurred vision and lack of coordination in the driver. However, these conditions may also be the very symptoms of the disease. In addition, the number of drug levels 2 and 3 taken together must also be considered. One of these drugs increases the risk by 14%, the two increases of 30% and 88% three. The pictogram is visible on each box of certain medical drugs. A notice inside the box, explain the risks relating to driving. This information is made compulsory by -laws.*

*Methadone and buprenorphine are classified level 2 : driving needs medical advice and level 2 is mentioned on the box with" Be very careful, do not drive without a medical advice"*

*During Substitution therapy, it is generally considered a patient well regulated with his therapy can drive in certain conditions and the advice is given individually by the therapist.*

## 1.17 Appendix 7 Questionnaire Greece

### B. LEGAL ASPECTS

*-Generally, there is a "zero tolerance" legislation in Greece, which includes all psychotropic substances. Law defines that "driving under the influence of any psychotropic agent is forbidden". In court, this "influence" and its subsequent impairment in driving ability have to be demonstrated, and occasionally this may become a very complicated procedure.*
*-In particular, substitution treatment is not mentioned in the law.*
*-In reality, patients who are receiving substitution treatment and possess a driving licence, use it, and drive.*
*-Limits of blood concentration exist only for alcohol and comprise three categories: up to a limit driving is allowed. Above that limit driving is restricted and sanctions in the form of fines are imposed. There is a third even higher limit beyond which, juridical measures are imposed.*
*-Epidemiological data exist for alcohol only, and provide information on the junction of alcohol in traffic accidents (injuries and fatalities).*

*The substitution treatment is not mentioned in the law* ☑

### C. MEDICAL ASPECTS

1. In your country, are there any experimental studies to determine the nature of the impairment produced by drugs used in substitution treatment, specifically their impact on ability to drive?

*No* ☑

2. Are there statistics (e.g. annual numbers of injured or killed drivers who tested positive for methadone, etc.) for prevalence of driving under the influence of drugs used in substitution treatment?

*No* ☑

### D. PRACTICAL ASPECTS

1. Are there any assessment procedures to define if patient in substitution treatment is able to drive cars?
*-There are not special assessment procedures to define if patients receiving substitution treatment are able to drive or not.*
*-Services delivering substitution treatment are not counted responsible for issues of traffic safety and for measuring and controlling their patients' ability to drive safe. This could be an issue of particular interest for potential intervention.*

2. What advice (if any) is given to drug dependent patients about their treatment and driving fitness?
*-Patients are advised that as long as they conform to the medical rules and norms concerning their substitution treatment, their driving ability is not impaired, so they can drive in safety. Any deviation from the treatment plan which involves missed doses, lapses and relapses, consumption of other drugs licit or illicit, readjustment of dosing, is considered as potentially capable to impair driving ability. On these occasions, patients are asked to consult with their therapists and key workers.*
*-The above described policy is not fully structured and therefore is not formally incorporated as a standard procedure.*

### E. ISSUES THAT REQUIRE SPECIAL ATTENTION IN APPLYING PRESENT POLICIES BASED ON NATIONAL EXPERIENCE.

*In relation to the issue of substitution treatment and driving, what are the issues that cause problems in applying the present procedures or that have not been yet covered and need attention in adjusting existing legislation and/or procedures in your country?*
*-Substitution treatment was introduced in Greece in 1996. Nowadays, fifteen years later, it constitutes an integral part of the national health system, and a top priority in the planning of health services for the addicted population.*
*Issues considering substitution treatment and driving have not yet drawn the necessary attention.*
*-Initiatives have to be undertaken in that particular domain, in order for legislation to be adjusted and for procedures to be constructed and implemented.*

### F. CONCLUSIONS AND RECOMMENDATIONS FROM NATIONAL EXPERIENCE.

Provide any advice based on the experience in your country with substitution treatment and road traffic safety.
*-It is both evidence based and clinically verificated, that stabilized patients in substitution treatment, are able to drive safely. Their right to possess and use a driving license has to be secured. Legitimisation, which for the time being is missing, is essential.*

ADDITIONAL INFORMATION

If there is any additional information that is relevant to topic of the questionnaire, for example, legal texts or scientific research and publication, please list it here.

*-A particular issue, arising from the limited cooperation between complementary services and from gaps in legislation and in administrative instructions, is the following: in the case of specific crimes and violations of "the drug-related law", the driving license of the offender is suspended.*
*At the end of any such case, for the license to be given back, there is a special procedure, and a certification of "detoxification" is asked. The point is that there are not authorized services and structured procedures for the provision of such a document. Therefore, people get confused, tension is increasing and there are accumulating complaints and resentment.*

## 1.18 Appendix 8 Questionnaire Ireland

### B. LEGAL ASPECTS

1. *It is illegal in Ireland to drive or to attempt to drive a mechanically propelled vehicle in a public place while under the influence of an intoxicant (intoxicant includes alcohol and drugs and any combination of drugs or of drugs and alcohol).*

2. *The substitution treatment is not mentioned in the law* ☑

### C. MEDICAL ASPECTS

1. In your country, are there any experimental studies to determine the nature of the impairment produced by drugs used in substitution treatment, specifically their impact on ability to drive?

*Don't know* ☑
*This question is being responded to by the Medical Bureau of Road Safety, Dublin.*

2. Are there statistics (e.g. annual numbers of injured or killed drivers who tested positive for methadone, etc.) for prevalence of driving under the influence of drugs used in substitution treatment?

*Don't know* ☑

**D. PRACTICAL ASPECTS**

1. Are there any assessment procedures to define if patient in substitution treatment is able to drive cars? *This question is being responded to by the Medical Bureau of Road Safety, Dublin.*

2. What advice (if any) is given to drug dependent patients about their treatment and driving fitness? *Department of Health and Children, Dublin is responding to this question.*

## 1.19 Appendix 9 Questionnaire Italy

**B. LEGAL ASPECTS**

*Italian law criminalizes driving under the influence of drugs, as in other European countries.*
*It is also required the absence of consumption and dependence on drugs to obtain and maintain driver's license.*
*At present, for drugs and driving, there is no regulation concerning a specific list of substances (either illicit or licit); therefore it refers to all drugs and psychotropic substances regulated by the Italian Law (Consolidated Law 309/90 modified by L. n.49/2006) with no cut-off regulation. The mere presence of drugs could certify unfitness to drive, in practice, according to the concept "zero-tolerance"; but this is not officially regulated, because there are not legislative decrees of implementation yet. With regard to driving in substitution treatment there is no law, but only guidelines, however not updated.*

2. The substitution treatment is not mentioned in the law ☑

*There are ministerial circulars and guidelines about substitution treatment in opiate dependence, but not specifically for driving.*

Yes, driving under the influence of substitution treatment is permitted by law ☑
If yes, please explain how exactly it is regulated in the law?

*It depends on the Local Committees.*
*There is no national uniformity.*
*For example in Florence is not allowed to drive in substitution treatment.*
*In other cities it is allowed, but only after medical control, and certification.*
*Rarely, in some cities, it's permitted at any dose of drug substitute.*

No, driving under the influence of substitution treatment is NOT permitted by law ☑
If no, please explain how exactly it is regulated in the law?

*See above*

## C. MEDICAL ASPECTS

1. In your country, are there any experimental studies to determine the nature of the impairment produced by drugs used in substitution treatment, specifically their impact on ability to drive?

*No* ☑

*There are no specific experimental researches concerning driving of individuals in substitution treatment. There are, instead, scientific articles that support the role of substitute drugs about the inability to drive.*

*Yes* ☑

*S.D. Ferrara, R. Snenghi: "Sostanze psicoattive, disabilità ed idoneità" in G.Giusti "Trattato di Medicina Legale" Vol. 4° Cedam, Padova, 2009 pagg. 1073-95*
*E. Bertol ."Aspetti giuridici – il Codice della Strada" in E. Bertol "Analitica Tossicologica. Aspetti tecnici, interpretativi, giuridici e deontologici" Esculapio Ed. Bologna, 2011 pagg. 91-118*

2. Are there statistics (e.g. annual numbers of injured or killed drivers who tested positive for methadone, etc.) for prevalence of driving under the influence of drugs used in substitution treatment?

*Yes* ☑ *(very rarely)*
*If yes, please indicate the results or make a reference to relevant publication.*

*In a study about alcohol and illicit drugs among 554 subjects involved in road crashes in Florence, Italy, 0, 4% were positive for methadone (F. Mari et al. Indian Journal Forensic Medicine & Toxicology (2009), 3, 30, 32*

## D. PRACTICAL ASPECTS

1. Are there any assessment procedures to define if patient in substitution treatment is able to drive cars?

*There are only studies referred to general procedures regarding drug interactions with driving*

2. What advice (if any) is given to drug dependent patients about their treatment and driving fitness?

*Of course, the recommendation to use caution when driving*

## E. ISSUES THAT REQUIRE SPECIAL ATTENTION IN APPLYING PRESENT POLICIES BASED ON NATIONAL EXPERIENCE.

In relation to the issue of substitution treatment and driving, what are the issues that cause problems in applying the present procedures or that have not been yet covered and need attention in adjusting existing legislation and/or procedures in your country?

*As you can see below, the main problem is lack of uniformity among the Local Committees of the different cities in Italy because, at the moment, although there are recent legal directives, we are waiting for implementation decrees.*

### F. CONCLUSIONS AND RECOMMENDATIONS FROM NATIONAL EXPERIENCE.

Provide any advice based on the experience in your country with substitution treatment and road traffic safety.

*As noted above, there are ministerial recommendations for fitness to drive in case of individuals in substitution treatment, even if each local committee acts differently.*
*The aim is the achievement of a uniform national regulation established by law.*
*A rule might be to assess in each case the individual controlled stabilization of the state of dependence and ability to drive, with close follow-up with a medical control. In addition, dosage of substitute drug has to be deal with: it is useful to establish a limit for individuals requiring guide license.*
*More strictly, it could be a precautionary measure, in the spirit of prevention of road accidents and traffic safety, no granting driving license during the use of substitute drugs, especially for methadone and buprenorphine, considered illegal drugs causing impairment to driving ability. Italy is working to standardize the protocols to check the driving capability (and in particular in cases of substitution treatment) in order to grant the driving license and to avoid the migration of users from a Local Committee to another, from a more strict one to a less severe one. And this should also be uniform throughout Europe.*

## 1.20 Appendix 10 Questionnaire Lithuania

### B. LEGAL ASPECTS

*1. Lithuania has "zero-tolerance" legislation for driving under influence/use/intoxication by drugs. The driver will be punished if the drug will be detected after test. The drug concentration in the blood does not have any impact for the penalty size or type.*

*2. The substitution treatment is not mentioned in the law* ☑

### C. MEDICAL ASPECTS

1. In your country, are there any experimental studies to determine the nature of the impairment produced by drugs used in substitution treatment, specifically their impact on ability to drive?

*Don't know* ☑

2. Are there statistics (e.g. annual numbers of injured or killed drivers who tested positive for methadone, etc.) for prevalence of driving under the influence of drugs used in substitution treatment?

*No* ☑

### D. PRACTICAL ASPECTS

1. Are there any assessment procedures to define if patient in substitution treatment is able to drive cars?

*No* ☑

2. What advice (if any) is given to drug dependent patients about their treatment and driving fitness? Advice is - *Do not drive a car.*

## 1.21 Appendix 11 Questionnaire Netherlands

### B. LEGAL ASPECTS

What is the relevant background information to describe the present situation in your country pertaining to the drugs and driving problems in general and to substitution treatment in particular? For example, introduction of "zero-tolerance" legislation, epidemiology of driving under influence of drugs in accidents, limits of blood concentration of drugs (either illicit or licit) which are acceptable or unacceptable for driving, etc.

Does the legislation in your country allow patients in substitution treatment to drive a car?

*The substitution treatment is not mentioned in the law* ☑

*No, driving under the influence of substitution treatment is NOT permitted by law* ☑
*If no, please explain how exactly it is regulated in the law?*

*In our "Wegenverkeerswet" (Roadtrafficlaw) there is an article that says that it is punishable to drive under the influence of a substance that can have effect on the ability to drive. This substance can be drugs but also medicines, alcohol.*

### C. MEDICAL ASPECTS

1. In your country, are there any experimental studies to determine the nature of the impairment produced by drugs used in substitution treatment, specifically their impact on ability to drive?

*Don't know* ☑

2. Are there statistics (e.g. annual numbers of injured or killed drivers who tested positive for methadone, etc.) for prevalence of driving under the influence of drugs used in substitution treatment?

*No* ☑ *There is some estimation for drugs, not specified for methadone.*

### D. PRACTICAL ASPECTS

1. Are there any assessment procedures to define if patient in substitution treatment is able to drive cars? No, such patients are told not to drive.

2. What advice (if any) is given to drug dependent patients about their treatment and driving fitness? *That they are not allowed to drive.*

### E. ISSUES THAT REQUIRE SPPECIAL ATTENTION IN APPLYING PRESENT POLICIES BASED ON NATIONAL EXPERIENCE.

In relation to the issue of substitution treatment and driving, what are the issues that cause problems in applying the present procedures or that have not been yet covered and need attention in adjusting existing legislation and/or procedures in your country?
*It is problematic to develop a selection instrument that detects all kind of drugs, without invading someone's physical integrity.*

### F. CONCLUSIONS AND RECOMMENDATIONS FROM NATIONAL EXPERIENCE.

Provide any advice based on the experience in your country with substitution treatment and road traffic safety.

### ADDITIONAL INFORMATION

If there is any additional information that is relevant to topic of the questionnaire, for example, legal texts or scientific research and publication, please list it here.

*In the Netherlands there are about 12.000 patients in substitution treatment. These patients usually don't drive cars or other motor vehicles. Maybe they ride on a bicycle. In the Netherlands driving under the influence of methadone is no issue.*

## 1.22 Appendix 12 Questionnaire Norway

### B. LEGAL ASPECTS

1. *From 01.01.2012 Norway will include 20 drugs in the Road Traffic Act in addition to alcohol with a low limit and limit of impairment.*
*Driving with BAC > 0.02 % is illegal 1.*

2. Yes, driving under the influence of substitution treatment is permitted by law ☑
If yes, please explain how exactly it is regulated in the law?

*Exemption from the law for persons in substitution treatment (with methadone or buprenorphine) if the following requirements are met:*
*- Treatment under proper supervision and control with known physician*
*- Stable dose > 6 months*
*- No use of sedative drugs*
*- No use of illicit drugs ≥ one year*

*Applicants must commit to absolute abstinence from drug use including sedative or anaesthetic drugs, and follow scheduled controls. Immediate onset notification is required in case of recurrence. If there is significant risk of recurrence a driving license or exemption should not be recommended.* [4]

### C. MEDICAL ASPECTS

1. In your country, are there any experimental studies to determine the nature of the impairment produced by drugs used in substitution treatment, specifically their impact on ability to drive?

Yes ☑
If yes, please indicate the results or make a reference to relevant publication.

Fredheim et al. 10 performed 3 neuropsychological tests in non-malignant pain patients after switching from morphine to methadone. No consistent improvement was detected, neither immediately after the switch to methadone nor at the three-month follow-up evaluation.

2. Are there statistics (e.g. annual numbers of injured or killed drivers who tested positive for methadone, etc.) for prevalence of driving under the influence of drugs used in substitution treatment?

Yes ☑
If yes, please indicate the results or make a reference to relevant publication.

*Bramness et al. 8 linked information from the Norwegian Prescription Database on any prescription of methadone and benzodiazepines, the Norwegian Road Accident*

*Registry on motor vehicle accidents involving personal injuries and the Central Population Registry on demographical information on all residents in Norway. A total of 4626 person years on methadone prescription were observed, and methadone exposed patients experienced 26 accidents involving person injury during the 29 months observation period. Among male drivers receiving methadone the SIR (standardized incidence ratio) was 2.4 (95 % CI 1.5-3.6) for traffic accidents with person injuries, not differing significantly when excluding exposure to benzodiazepines. (In press)*

## D. PRACTICAL ASPECTS

1. Are there any assessment procedures to define if patient in substitution treatment is able to drive cars?

*Please see "B. legal aspects".*

2. What advice (if any) is given to drug dependent patients about their treatment and driving fitness?

*Abstinence of other drugs required.*

## E. ISSUES THAT REQUIRE SPECIAL ATTENTION IN APPLYING PRESENT POLICIES BASED ON NATIONAL EXPERIENCE.

In relation to the issue of substitution treatment and driving, what are the issues that cause problems in applying the present procedures or that have not been yet covered and need attention in adjusting existing legislation and/or procedures in your country?

*Six months on a stable dose could be a long period, in relation to rehabilitation, for subjects in substitution treatment to have to wait to be allowed to drive. Total abstinence of other drugs can be difficult in some subjects as they could be prescribed e.g. sleeping medication, but it is an absolute requirement to be allowed a drivers licence. An individual evaluation rather than general guidelines could be a good alternative to the current practice.*

## F. CONCLUSIONS AND RECOMMENDATIONS FROM NATIONAL EXPERIENCE.

Provide any advice based on the experience in your country with substitution treatment and road traffic safety.
*The literature in this field appears too limited to draw clear conclusions regarding maintenance use and driving. Evaluation of individual performance of maintained patients seems with the present knowledge to be the only useful procedure to approach the question of fitness for driving.*

## ADDITIONAL INFORMATION

If there is any additional information that is relevant to topic of the questionnaire, for example, legal texts or scientific research and publication, please list it here.

*Bernard et al. [6] investigated apprehended Norwegian drivers that had methadone in their blood at the time of apprehension over the period 2001-2006. Methadone was the only psychoactive drug detected in blood in only 10 cases out of 635 drivers identified. The extensive use of other drugs among this group makes it more difficult to assess the effects of methadone and buprenorphine treatment alone.*

## 1.23 Appendix 13 Questionnaire Slovakia

### B. LEGAL ASPECTS

1. *The legislation framework for regulation of car driving under the influence of drugs is adjusted under the Legal Act No. 8/2009 Call on Road Traffic. Driving under the influence of drugs (licit or illicit) is in the Slovak Republic prohibited; the "zero tolerance" is the basic principle for legal regulation. Use of alcohol or other psychoactive substances is according to the law understood as a serious harm of safety and smoothness of road traffic. Violation of law is linked to the infringement law and criminal law.*

*In the legal act 8/2009, there is exactly expressed that the driver mustn't:*

- *take alcohol or any addictive substances* during the car driving*
- *drive a car in the period after he/she took alcohol or other addictive substantives and these substances could be still in drivers organism*
- *drive a car in the period after he/she took a medicament (prescription drug) and this medicine could decrease the ability to drive a car.*

*The driver also mustn't hand in the car driving to the person who is under the influence of alcohol or other addictive substances.*

*Generally it is applicable that the police are authorized to appeal the driver to subordinate of examination if he/she isn't under the influence of alcohol or other addictive substances or medicine which could degrease the driving ability. The same is applicable by the examination of accidence. By examination of use of alcohol the alco-tests are used, the other addictive substances are examined by medical control in health institutions. Under the request of medical or control authority the toxicological examination (individual or grouped screening of psychoactive substances) is realized. The toxicological examination could identify concrete substance (also methadone) and its blood concentration. The use of alcohol up to limit 0, 2 ‰ is specially examined and it is comprehensive assessed (toxicology and medical) if alcohol was used.*
*Actually prepared amendment of legal act 8/2009 is proposing to introduce the obligation to toxicology examine the biological material. This amendment is aimed to exactly confirm if alcohol or other addictive substances were used and if the positive result is found out, the concentration of substance will be also detected. The amendment also proposed to decrease the limit of use of alcohol up to 0, 1 ‰ by mentioned toxicological examination.*

** Addictive substances under legal act 8/2009 are defined as: alcohol, narcotic drugs, psychotropic substances and other substances which are able to negative influence human psychic or body-control or sense-perception or social behaviour of person.*

*Annually are reported the data about offences (connecting to the article No. 289 of Criminal Code) which are perpetrated under the influence of addictive substance by performance of work or other activity where the life or health or damage of possession could be threaten. The data are reported collectively for all of addictive substances, the differentiation between drugs (also legal and illegal) is not applicable. Even though these data could be found out (concerning the realized toxicological examination) if the special demand arises.*

2. The substitution treatment is not mentioned in the law ☑

No, driving under the influence of substitution treatment is NOT permitted by law ☑
If no, please explain how exactly it is regulated in the law?

*In the Slovak Republic the "zero tolerance" for illicit drugs, also for opiate agonists is applicable. The substitution treatment is not mentioned in the law; generally an alcohol and drug addiction excludes the health ability to drive a car. The legal Act 8/2009 and its execution recommendation concretize relation between alcohol and drug*

*addiction and health ability. Legal acceptation of health ability to drive isn't possible when the person is alcohol or drug+ addicted. If a person was in the past addicted to alcohol the health ability is possible to accept only on the base of results of specialized medical control and under the condition that the person consistently and continually abstinences at least 2 years and is regularly subordinated to medical control of alcohol addiction and results of medical control doesn't excluded health ability. When the person was in the past drug addicted the health ability is possible to accept only on the base of specialized medical control and under the condition that he/she is regularly subordinated to medical control of drug addiction and results of medical control doesn't excluded health ability.*

*+ Drug addiction is understood as: to be addict or to regularly abuse the other addictive substances or medicaments or their combinations*

## C. MEDICAL ASPECTS

1. In your country, are there any experimental studies to determine the nature of the impairment produced by drugs used in substitution treatment, specifically their impact on ability to drive?

*No* ☑

2. Are there statistics (e.g. annual numbers of injured or killed drivers who tested positive for methadone, etc.) for prevalence of driving under the influence of drugs used in substitution treatment?

*No* ☑

*The data are reported jointly in accordance to the article No. 289 of Criminal Code. Differentiation for each individual psychoactive substance is not applicable (only if a special demand arises).*

## D. PRACTICAL ASPECTS

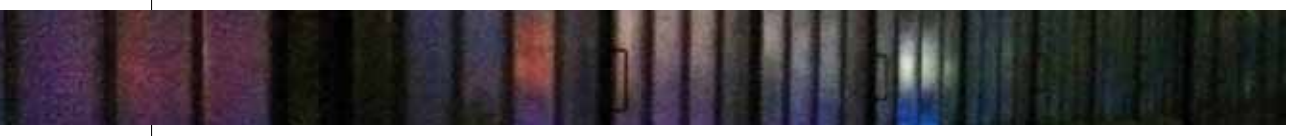
1. Are there any assessment procedures to define if patient in substitution treatment is able to drive cars?

*Special assessment procedures concerning substitution treatment doesn't exist.*

*As it was mentioned before emphasize is generally given to the individual assessment of complex health ability of person to drive a car (assessment of physical and mental ability). When it is necessary the health ability of person is conditioned to the subordination of regularly medical control (connecting to the addictions the specialized medical control of alcohol and drug addiction is required). The legal act 8/2009 specified mental ability as the ability to drive a car without decreasing, disrupting or limiting the minimal level of driver's physical abilities.*

2. What advice (if any) is given to drug dependent patients about their treatment and driving fitness?

*Connection to the "zero tolerance" the patients are guided that they don't have to drive a car.*



## 1.24 Appendix 14 Questionnaire Sweden

### B. LEGAL ASPECTS

1. *Sweden has zero-tolerance legislation when it comes to drugs in the blood under or after driving a motor vehicle. The law makes an exception from the zero tolerance for prescribed drugs (medical treatment).*
*The Transport Agency makes deep studies of all fatal accidents. Not all drivers are tested, and many that have consumed alcohol are not tested for drugs. However during the years 2005-2010 100 drivers had used narcotics, out of 1462 drivers totally.*

2. The substitution treatment is not mentioned in the law ☑

Yes, driving under the influence of substitution treatment is permitted by law ☑
If yes, please explain how exactly it is regulated in the law?
*The law makes an exception from the zero tolerance for prescribed drugs (medical treatment).*

### C. MEDICAL ASPECTS

1. In your country, are there any experimental studies to determine the nature of the impairment produced by drugs used in substitution treatment, specifically their impact on ability to drive?

*Don't know* ☑

2. Are there statistics (e.g. annual numbers of injured or killed drivers who tested positive for methadone, etc.) for prevalence of driving under the influence of drugs used in substitution treatment?

*No* ☑

### D. PRACTICAL ASPECTS

1. Are there any assessment procedures to define if patient in substitution treatment is able to drive cars?

*Yes, this is a part of the substitution treatment programmes.*

2. What advice (if any) is given to drug dependent patients about their treatment and driving fitness?

*In the end it is the responsibility of the patient to decide if he or she is able to drive. The advice is not to drive in the beginning of the programme. The patient should always take this kind of decisions after consulting the responsible doctor.*

### E. ISSUES THAT REQUIRE SPECIAL ATTENTION IN APPLYING PRESENT POLICIES BASED ON NATIONAL EXPERIENCE.

*There are not, as far as I know, not any major problems in relation to the existing regulation.*

### F. CONCLUSIONS AND RECOMMENDATIONS FROM NATIONAL EXPERIENCE.

*Our system is based on a restrictive regulation on substitution treatment and with a strict medical supervision. That is a guarantee that all patients are well informed and that they have no room for experiments on their own concerning prescriptions.*

# 2 Analysis of the different practices and approaches on road traffic safety and substitution treatment

The mobility provided by road transport, particularly the passenger car, allows many modern Europeans to enjoy a lifestyle characterized by flexibility and independence. However, if we count up the lives lost and injuries inflicted in road traffic accidents, it is clear that this comes at a price, with the most recent statistics revealing that more than 40 000 people die on European roads each year, while a further 1.7 million are injured. No less than a quarter of these deaths, some 10 000 per year, are estimated to be caused by drink-driving (1). And although alcohol is by far the most prevalent and well documented psychoactive substance affecting drivers, concerns have been mounting about increasing reports of road deaths linked to illicit or medicinal drugs. Public awareness of the role of psychoactive substances other than alcohol in road traffic accidents has increased and pressure to respond to this problem is accumulating.

Most European countries take one of two approaches to define the offence of driving under the influence of drugs. Eleven countries only penalize impaired driving, whether caused by illicit drugs or medicines. Eleven other countries have adopted a 'zero-tolerance' policy, penalizing any driving after drug-taking. In seven countries, these two approaches are combined in a tiered response to drug driving offenders. Some 'zero-tolerance' countries make no distinction between psychoactive medicines and illicit drugs, others do (2)

Concern is also growing about the possible impact of the increasing numbers of drug users receiving opioid substitution treatment. Maintenance treatment with methadone and buprenorphine has become a main approach in the stabilization and rehabilitation of patients with heroin dependence. As the patient improves the question concerning the possibility of driving a car often arises, as driving can be crucial for the return to normal life. According to the results from the overview of the different approaches concerning substitution treatment and driving in Europe (PPG/RTD (2011) 5) it is permitted to drive during substitution treatment in 9 out of 13 countries. In 5 of these countries the patient can choose to drive, usually after information from the therapist. Many countries have zero-tolerance legislation for driving under the influence of drugs, but methadone or buprenorphine are not specified in the law. In Italy there is no national uniformity with different cities adopting different approaches, whereas in Greece there seems to be a lack of structured procedures for certain issues concerning the suspension of the driving license after drug related crimes. In Norway and France substitution treatment is mentioned in the law which is not the case for other countries. Evidently the need for harmonizing policies in a European level, taking into account national specificities is increasing.

## 2.1 Zero tolerance policy

Adopting a zero tolerance policy towards driving under the influence (DUI) of any psychotropic substance in addition to alcohol, including substitution treatment, gives a clear message to drivers and secures in theory road traffic safety. Such a policy addresses the accumulating social pressure due to attention given to this issue by the media. Drug addicts are persons usually stigmatized and marginalized and such a policy usually comes as a "natural" consequence of their heretic life style.

The information from prescribing doctors to patients has to be clear and the same time the police authorities have to adopt road-side detection methods which are accurate, cost effective and are not invasive as far as physical integrity is concerned.

The concept of opioid addiction as a medical disorder was supported by different studies showing that opioid addiction has a reasonably predictable course, similar to chronic conditions such as diabetes, hypertension, and asthma (3) (McLellan et al. 2000). The constitutional right to treatment has to be secured like in other medical disorders. By prohibiting driving during substitution treatment, obstacles are created especially for people in rural areas to enter and continue treatment. Psychological obstacles created by the limitation of driving should not be underestimated and may also lead patients to reject treatment.

Zero tolerance policy toward substitution treatment and driving, discriminates and stigmatizes patients in need of such therapy if we take into consideration that there are other medical disorders that can have considerable effects on the capabilities of drivers, but still driving is not prohibited. (E.g. schizophrenia, epilepsy, diabetes) There are countries where legislation regulates driving under certain medical conditions where in others this issue is generally addressed without adopting special procedures.

Another issue which has to be given due consideration is the fact that there are people suffering from opioid addiction and possess a driving license. If by entering substitution treatment, restrictions to driving are put by the law, this will act as a deterrent, meaning that these people will not chose a treatment program and they will continue to drive with increased risks for road safety. Intoxication and withdrawal symptoms and the parallel use of other psychotropic drugs prescribed or illegal is the case for the majority of opioid addicts and hampers seriously fitness to drive. It is of crucial importance for harm reduction which concerns road safety too, to have the majority of opioid addicts in substitution therapy.

The ability to drive a car in today's Europe is rudimental for social and professional life. People attending substitution treatment programs, apart from addressing their physical dependence with the aid of buprenorphine or methadone, also have diverse needs for social reintegration. Taking into account that patients in substitution treatment are usually between 20 and 40 years old, the ability to drive a car plays a crucial role for their social and professional rehabilitation.

## 2.2 Regulating policy for driving and substitution treatment

Moving away from the zero tolerance policy there is accumulating scientific evidence allowing the adoption of strategies that regulate driving during substitution treatment.

There are countries that adopt a zero-tolerance policy in general, but make an exception for prescribed drugs (medical treatment) like Sweden and France. In others driving under substitution treatment is allowed after consultation with the physician providing the therapy, or the key worker. Norway is the first country in the world where legislative limits for driving under influence of 20 non-alcohol drugs, including methadone and buprenorphine, are implemented in the law from 01.02.2012. However the law stipulated that this regulation does not apply for drivers who take the medicinal drug under a prescription regime.

The philosophy underlying the regulating approach is to promote and support the ability to drive, which in today's Europe is crucial for social existence, for people with physical and medical handicaps alike. The right to treatment is established especially in areas where public transport networks are not well developed like rural areas. Rehabilitation efforts, social and professional are enhanced, since the majority of patients in substitution treatment are in their working age when driving ability is indispensable.

By supporting the ability to drive, substitution treatment programs are more attractive and retention rates for patients are bigger, promoting the harm reduction concept both for individuals and road traffic safety. Drug addicts are a subgroup with certain characteristics where risk communication strategies concerning road safety can be designed. Inside treatment, there is better assessment of individual driving performance and there is the possibility for early interventions when relapses or other problems occur. Linkage between substitution treatment and driving rehabilitation programs can offer great benefits too.

In order to adopt a regulating policy for driving under the influence of drugs including substitution medication, cut-off limits should be determined. These limits should be similar to the commonly understood blood alcohol concentration (BAC). This would give a simple legal threshold to indicate at what stage impairment becomes dangerous for users or for those around them.

Yet while the BAC figure has become generally accepted after decades of research, Member States have refused/resisted attempts by the EU to harmonize it (similarly, the issue of testing at random or only on suspicion, even for excess alcohol, still sharply divides them). In addition, it is difficult to apply the BAC parallel to other psychoactive substances because of the vastly different pharmacological natures of the range of substances involved, the limitations of experimental and epidemiological research in trying to determine such a cut-off level, the ethical considerations involved in its enforcement and the question of combining or separating drug abuse control and road safety measures. Specifically, it is unacceptable to some that a driver be punished for driving with an amount of drug that has no relevant effect on driving, while it is equally unacceptable to others to condone illicit drug use by stating that up to a certain threshold, it will not be punished.

Especially for substitution treatment patients, cut-off limits are completely different since the effect of substitution medicines on fitness to drive for stabilized patients is of minor importance compared to drug naïve persons.

The creation of dosage levels is per se not necessary to establish civil or criminal liability. Civil liability can be established on the basis of a general warning or caution on the risk of driving under the influence of a certain substance. Criminal liability can also be established without specific dosage levels; however the threshold for establishing liability under criminal negligence holds a higher threshold in personal accountability justifying conviction. On the other hand, the establishment of blood concentration levels will make enforcement of traffic laws more efficient and easier. Additionally the implication of cut-off levels along with the provision of applying special documentation to substitution treatment patients can make the job of traffic police easier to identify drivers who abuse substitution medicines.

The question to establish levels for illicit drugs, as opposed to outlawing driving under the influence of illicit drugs per se, is primarily a political choice. The legislation adopted by Norway and its implementation should be assessed as to serve as a possible model for other countries in the future. Feedback is necessary concerning new problems that may arise and the cost effectiveness of this approach. Alcohol driving remains the major threat for road traffic safety and the diversion of valuable resources towards other directions is an issue that should be dealt with great attention.

Another important issue that has to be mentioned is the tendency of practitioners not to apply the regulations even though they exist in both approaches. Impairment of driving skills due to a medicinal treatment puts both doctors and patients in a difficult position. As a result experience from clinical practice reveals that there is widespread reluctance among practitioners to avoid confrontation with patients and choose not to deal with the issue efficiently.

Finally choosing not to regulate the issue of substitution treatment and driving, leads to the continuation and augmentation of existing problems. Substitution treatment is becoming the treatment of choice for opioid addiction and the number of patients in substitution programmes is growing. Free mobility inside E.U for personal, professional or other reasons in a modern, reliable, safe and efficient transport system capable of upholding sustainable development is a goal that has to be reached. Towards that direction initiatives have to be taken for national legislations to be harmonized and for procedures to be constructed and implemented in different E.U member states.

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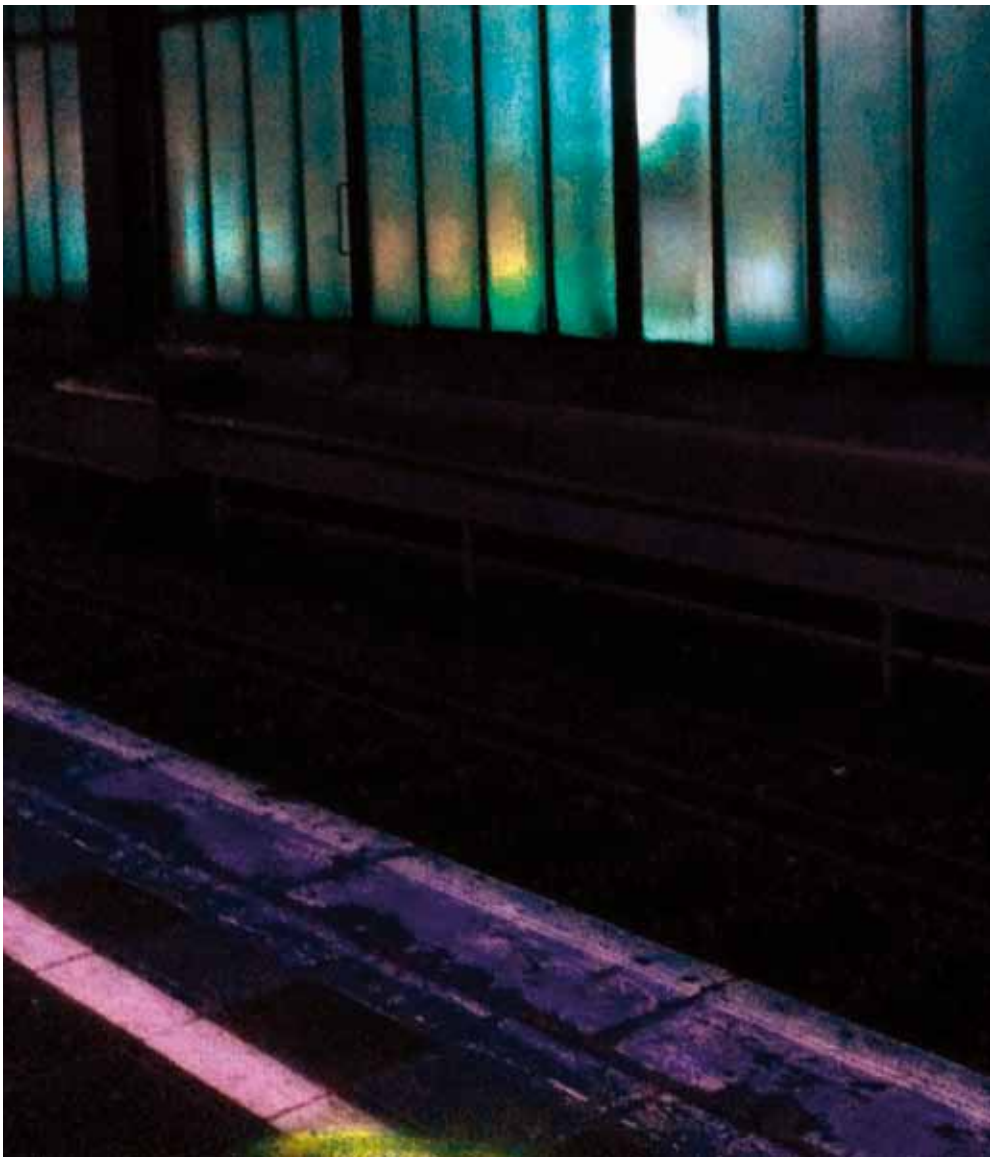

# 3 Summary of existing evidence of the effects of different substitution drugs on the ability to drive

Within the DRUID project a systematic review was performed on experimental studies on psychomotor and cognitive performance after intake of opioids, including methadone and buprenorphine. A summary of the relevant findings will be presented in the following). A full review including references can be found in the original report (DRUID project, Deliverable 1.1.2C, 2011, www.druid-project.eu).

## 3.1 Results

### 3.1.1 Effects of single dose methadone/buprenorphine on healthy volunteers

#### 3.1.1.1 Methadone

3 studies dealt with single dose of methadone to drug naïve subjects, and all 3 studies found impairment. A total of 5 tests were performed, and impairment was found in 3 of the tests. Impairment was found in a dose range from 5 to 10 mg methadone p.o. (n = 7-12). Dose related impairment was observed for one of the tests.

#### 3.1.1.2 Buprenorphine

5 studies (n = 7-16) dealt with single dose of buprenorphine to drug naïve subjects, and all studies found impairment. A total of 20 tests were performed, and impairment was found in 18 of the tests. Impairment was found in a dose range from 0.075 mg to 0.6 mg i.v. Some dose related impairment was observed.

### 3.1.2 Use in patients treated chronically

#### 3.1.2.1 Methadone maintenance patients compared to control groups

28 studies dealing with performance of methadone maintenance patients compared to various control groups were included. Sizes of the groups were from 9 – 54 subjects (dose range 2-150 mg). In 27 studies some significant impairment was found, in some studies in all tests performed. A total of 220 tests were performed, and impairment was observed in 104 of the tests. The percent of impaired tests was calculated for each of the 28 studies, ranging from 0 to 100 percent. The mean percentage of significantly impaired tests was 44 %. 2 studies also observed some improvement in performance.

When the studies clearly indicating the duration of treatment were divided into those with patients treated for more than 1 year and those with shorter treatment , the percentage of findings of impairment were 63 % (n = 9) and 56 % (n = 4) respectively, not significantly different.

When the studies were divided in those where the mean daily methadone dose was above 70 mg and those with lower daily dosage, the percentage of findings of impairment were 40 % (n =12) and 52 % (n = 14) respectively, not differing significantly.

In some of the studies methadone patients were compared to ex-heroin users only or to a control group of matched non-users as well. Methadone maintained patients always performed worse than controls, and similar or worse than ex-users in the 7 studies that allowed such comparisons.

Use of other drugs that could be impairing at the time of testing was another important point which was looked for in 20 studies, and the drug positives (urine analysis) were excluded from the study. The percentage of findings of impairment in these 20 studies were 55 %, in the other studies where side use was not corrected for, not measured or not further specified, the percentage of findings of impairment was 32 %. In one study, however, where a methadone group without use of other drugs, was compared with the whole group of methadone users with 2/3 using other drugs, the performance in those using methadone was markedly better.

#### 3.1.2.2Performance before and after long-term methadone intake

4 studies dealt with performance before and after long-term methadone intake, and 2 studies found impairment. A total of 16 tests were performed, and possible impairment was found in 6 of the tests (n = 7-30, dose range 10-400 mg). One study found improvement of several tasks after daily dose of methadone.

#### 3.1.2.3Single dose methadone to methadone maintenance patients

10 studies dealt with single dose of methadone administered to methadone maintenance patients, and 7 studies found impairment. A total of 50 tests were performed, and impairment was found in 10 of the tests. Impairment was found after a dose ranging from 10 to 120 mg methadone p.o., and after an addition of 50 or 100 % of daily dose (n = 10-39). Some dose related impairment was observed.

#### 3.1.2.4 Single dose methadone to current users of opiates/opioids

One study dealt with single dose of methadone (dose range 15-60 mg) to current users of intravenous heroin, and one test was performed. No impairment was found (n = 5).

#### 3.1.2.5 Buprenorphine maintenance patients compared to control groups

7 studies dealt with performance of buprenorphine maintenance patients compared to control groups, and 5 studies found impairment. A total of 44 tests were performed, and impairment was found in 14 of the tests (32%). Impairment was found at a maintenance dose range of 6.78-15.8 mg buprenorphine/day (n = 15-40). No clear dose response patterns were observed.

#### 3.1.2.6 Buprenorphine maintenance patients compared to methadone maintenance patients

8 studies dealt with performance of buprenorphine maintenance patients compared to methadone maintenance patients. Two studies showed that buprenorphine and methadone patients performed equally (buprenorphine 9.4-14.4 mg, methadone 48.1-74.3 mg). 6 studies showed that buprenorphine patients performed better than the methadone patients (buprenorphine dose range 0.2-20 mg, methadone dose range 2-150 mg). A total of 59 tests were performed, and 10 of the tests showed that buprenorphine patients performed better than methadone patients.

#### 3.1.2.7 Single dose buprenorphine to methadone or buprenorphine maintenance patients

7 studies dealt with single dose of buprenorphine to methadone or buprenorphine maintenance patients. 2 studies found impairment and 2 studies observed improvement of performance. A total of 21 tests were performed, and impairment was found in 2 of the tests. Impairment was found in a dose range from 2 to 13.4 mg (n = 13-20). No clear dose response patterns were observed. Improvement was observed in 3 out of 21 tests, in a dose range from 4 to 13.4 mg (n = 19-20).

#### 3.1.2.8Single dose buprenorphine to current users of opiates/opioids

3 studies dealt with single dose of buprenorphine to non-physically-dependent opioid abusers, and one study found impairment. A total of 4 tests were performed, and impairment was found in one of the tests. Dose related impairment was observed after 0.4-0.8 mg i.m. (n = 7).

## 3.2 Limitations

Before trying to summarize and conclude from the results presented below it is important to focus on some limitations which appear to be quite common for the papers included.

There could be marked differences between the subjects selected to methadone or buprenorphine treatment. It is important to realize that studies with methadone or buprenorphine treated subjects are not randomized, and that factors determining the selection to methadone or buprenorphine treatment groups could possibly be the explanation for all differences observed between the groups. The choice of drug depends on previous (drug) history and characteristics of the patient and these differences may be reflected in the various tests performed. Buprenorphine administered to pain patients is, however, an exception.

In many studies on methadone and buprenorphine maintained patients, the individual dosage reported for a group represents a wide range, the highest dose sometimes being close to 10 times higher than the lower. This fact would lead us to assume that drug blood concentrations in such a group of patients would represent an interindividual difference of the same order of magnitude, maybe even larger as there is a wide inter- and intra-individual variation in drug blood concentrations for a given dosage of both methadone and buprenorphine. Furthermore none of the studies reviewed on maintenance patients measured blood drug concentration in a study with performance tasks.

Furthermore none of the studies on maintained patients reported results for subgroups or individuals on different dosage levels. Even if we could have made some theoretical calculation on blood drug concentrations in patients on steady state long-term dosing, we would not have had performance data corresponding to that concentration range. Such a concentration range would probably have had a span of 3 times (i.e. the highest concentration divided by the lowest) making its usefulness rather limited.

## 3.3 Summary results

In spite of the limitations prevailing for the studies reviewed some tentative conclusions can be made:

### 3.3.1 Single dose of methadone and buprenorphine to naïve subjects

Single doses of methadone and buprenorphine appears to be followed by impairment in drug naïve subjects, as 3 of 5 tests that examined the effects of single dose methadone to drug naive healthy volunteers found impairments of methadone doses up to 10 mg, and 18 of 20 tests that examined the effects of single dose buprenorphine to drug naive healthy volunteers found impairments of buprenorphine (0.075-0.6 mg kg i.v., 0.4 mg p.o., 0.3 mg i.m.).

### 3.3.2 Single dose of methadone and buprenorphine to current users of opiates/opioids

When single doses were administered to opiate/opioid abusers these acute effects were less pronounced. Single dose methadone was given to current users of opiates/opioids in one test, and no impairment was found. When single dose buprenorphine was given to current users of opiates/opioids, only one out of 4 tests performed found impairment. The only study

assessing the effect of daily buprenorphine dose in opioid dependents found no changes from predosing to post dosing on the test performed.

### 3.3.4 Single dose of methadone and buprenorphine to maintained patients

When single doses were administered to maintained patients the acute effects of methadone and buprenorphine also appeared to be less pronounced as 10 out of 50 tests found some dose-related effects for doses up to 120 mg methadone in methadone maintained patients. Only 2 out of 21 tests found impairment after doses up to 13.4 mg buprenorphine in patients maintained at methadone or buprenorphine. Furthermore, 3 out of 21 tests found improvement of performance after buprenorphine doses from 4 to 13.4 mg in buprenorphine maintained patients.

### 3.3.5 Methadone maintained patients compared to controls or pre-treatment status

When it comes to performance of methadone maintenance patients compared to controls, 110 out of 236 tests showed impairments. 4 studies have compared the performance before and after long term methadone intake, one of the studies found impairment and one study found improvement from baseline measures.

### 3.3.6 Buprenorphine maintained patients compared to controls

When it comes to performance of buprenorphine maintained patients compared to controls, 14 out of 44 tests showed impairment.

### 3.3.7 Buprenorphine maintained patients compared to methadone maintained patient

8 studies have compared the performance of buprenorphine maintenance patients to methadone maintenance patients. 10 out of 59 tests found a better performance under buprenorphine treatment. The differences between buprenorphine maintained and matched controls seemed less evident than for methadone, and individuals under buprenorphine treatment performed somewhat better than individuals under methadone treatment.

## 3.4 Discussion

A major problem in assessing the true impact of drugs on driving and overall traffic safety is that the variables being measured across studies vary significantly. In research reported in a growing global literature, basic parameters assessed, analytical techniques and drugs tested are simply not comparable due to the lack of standardization in the field. An expert panel recently recommended that alcohol effects on performance could serve as a standard reference to quantify impairments for many other drugs. It is a general lack of comparator drug in the studies reviewed. Only one study used alcohol as comparator drug. Especially for studies reporting no impairments, the lack of comparator drug is a considerable shortcoming.

The expert panel also recommended that researchers should use tests that have been validated to be sensitive to drug effects on driver performance, and to the extent possible, have demonstrated predictive validity of driving impairment. The problem is, however, how to do this for opioids. Another problem is to assess which type of tests that could be relevant for this patient group. Clearly real driving is the ultimate performance test, but is attention more important than visual functions in these subjects? Is motor performance less important than a psychological evaluation battery? One could argue that tests considered valuable in e.g. alcohol studies (the most studied drug in experimental and epidemiological traffic research) should be the tests most useful in studying relevant effects of opioids in relation to traffic safety. But we do not know whether opioids are potentially risky in traffic by the same (central nervous) effects as alcohol. Even if we postulate that the mechanisms are similar for

alcohol and opiates (which from a pharmacological point of view is quite unlikely), we would have difficulties in applying this type of approach to the present material. We have only one study where alcohol has been used as comparator drug. In all the other studies (n = 40, besides Mørland and Fishbain et al.) we have no data on how alcohol would have influenced the tests used in the particular setting of the experiments performed.

It is important to know the current and past drug-use history of all test subjects. Tolerance seems to be of great importance to draw into consideration for opioids like methadone and buprenorphine as there are not any clear dose response patterns like e.g. for alcohol. The majority of healthy volunteers included in the studies report some use of recreational drugs. In some of the studies the history of drug use is not well described. As such, the categorization of studies into groups based on the individual's opioid tolerance could be misleading. Also the use of drugs besides methadone and buprenorphine in maintenance patients is of importance, and such data were missing in many studies. Bernard et al. investigated apprehended Norwegian drives that had methadone in their blood at the time of apprehension over the period 2001-2006 (n = 635). Methadone was the only psychoactive drug detected in blood in only 10 cases out of 635 drivers identified. The extensive use of other drugs among this group makes it more difficult to assess the effects of methadone and buprenorphine treatment alone. It is important to control for an associated drug abuse/dependence of other drugs in studies where opioid abuse/dependence subjects are utilized. If the associated drug abuse/dependence is not controlled for, it could confound the results. Hauri-Bionda et al. found that the fraction of the methadone group screening positive for other psychoactive drugs in urine performed markedly worse than the remaining part of the group. The type of previous drug abuse/dependence is also potentially important to the neuropsychological impairment.

# 4 The relevance of driving under substitution treatment with respect to existing detection methods

DRUID project, Deliverable 6.2.1 (chapter 7.2, p 43-46) states the following:
“Regular checks for other drugs are indispensable. Hair analysis should be carried out every six months or urine screenings more frequently. Immunological tests are sufficient. Conformation analyses are necessary if patients deny positive results.”

Urine, oral fluid and hair testing is relevant with regards to the therapeutic approach of opioid substitution treatment, and patients in substitution treatment must be tested regularly. Collection of hair for analysis is a non-invasive procedure, the sample is easy to collect and hair is suitable to discover regular use. Urine analysis can detect single intakes. Oral fluid collection is also a non-invasive procedure and oral fluid can be used to detect single intakes.

Drug testing outside the treatment situation includes road-side testing. In relevance to road-side testing it is important to keep in mind that the detection method used must include methadone and buprenorphine. Immunological tests does not necessary detect these drugs. Detection methods may also vary between the matrixes used (urine, hair and oral fluid).

# 5 Aspects which are relevant to the rights of the patient, in particular the right to non-discrimination

The goal of this chapter is to discuss the issue of allowing patients in maintenance treatment to drive from a patients' rights perspective.

The starting point of this discussion should be the statement that substitution treatment of opioid dependency is a routine medication procedure applied to ill people. Drug dependency is an illness like other illnesses and patients should be treated without any discrimination practices. The only criterion for restriction of right to drive must be the importance of public interest. In case of driving the only one reason for restriction could be limitation of driving skills, if such limitation can be proved.

Drug dependency is one of the mental disorders classified by WHO under the psychiatric diagnoses chapter. Ethical recommendations of WHO for the legislation related to people with mental disorders can therefore also be applied to the drug dependent. In the WHO Resource book on mental health, human rights and legislation are formulated: "Legislation can also play an important role in ensuring that a person suffering from a mental disorder can participate in the community. Prerequisites for such participation include access to treatment and care, a supportive environment, housing, rehabilitative services (e.g. occupational and life skills training), employment, non-discrimination and equality, and civil and political rights (e.g. right to vote, drive and access courts)." (WHO, 2005).

Substitution treatment for opioid dependence is widely available in Europe and generally considered an important element in the response to this type of addiction (EMCDDA 2008). However, still in some countries this approach is considered controversial and sometimes viewed as condoning drug use. This probably creates the background for no equal treatment of patients of drug free treatment and substitution treatment. This kind of discrimination produces a lot of negative consequences. Maintenance treatment patients are considered to still be drug users, what justifies the limitation of their rights.

The restrictions related to driving by maintenance treatment patients are usually justified by public interest. The public interest in this context consist in right of all road traffic participants to be safe on the road, that means to eliminate from the road traffic the drivers who are not capable enough to drive, because being under influence of psychoactive substances for example. There is usually mentioned in this context that if even though the appropriate dose of substitution medicine does not impair driving skills, the substitution treatment patients quite frequently use also other illegal drugs or/and drink alcohol. Such kinds of behaviours increase probability of accidence, if it is related to driving. But there is no evidence that substitution treatment patients are more likely to drive under the influence of alcohol or illicit drugs than other categories of drivers.

As Capps and Ashcroft write in the EMCDDA Monograph: "From a human rights perspective" (Capps, Ashcroft 2009), the following principles could be taken to be requirements for treatment to be regarded as ethical:

- Human rights law should be clearly understood and prioritised over the competing claims of the public interest. A balance must be found between these competing claims and this should be expressed in the ethical values of autonomy, liberty, privacy and consent;
- Restricting individual rights in the public interest must only be done for compelling reasons based on empirical, clinical and scientific evidence.

While there is no strong and conclusive empirical scientific evidence that substitution medicines like methadone or buprenorphine impair diving skills, there still exist doubts if patients using these medicines should be allowed to drive. These doubts are related more to the

patients' psychological profiles, habits and life style than to the psychoactive properties of medicine used in maintenance treatment. Such approach assumes that drug dependent persons cannot be trustworthy and therefore cannot be allowed to drive.

Neuroscience research on addiction does not prove that addicts lack autonomy: while their autonomy is clearly impaired in some situations, particularly during withdrawal or intoxication, drug addicts preserve some degree of control over their decisions. One of the aims of treatment should be to increase patient decision-making capacity and autonomy (Spriggs, 2005). Therefore we cannot treat drug addicts as incapacitated individuals. They are able to behave in a responsible way and they should be forced for such kind of behaviour (West, 2006). The luck of trust could be the factor that facilitates relapse. Patients in maintenance treatment is exposed to relapse and we cannot be sure that he/she don't take other drug, but even if it would happen the patient is still able to avoid driving in such circumstances. Some additional control measures could be considered. For instance linking treatment program with driving licence authority in terms of information exchange, but always it should be in line with articles 1 and 10 of Council of Europe Convention on Human Rights and Biomedicine (Council of Europe, 1997).

There is no obvious neurobiological justification for the fact that some psychoactive substances are legal while others are not. Nor does the legal status of these drugs necessarily directly correspond to the relative harms caused by their current levels of use (Room, 2007). In consequence drug addicted patients should not be treated differently than alcohol dependent patients. In most countries there are not special regulations related to the driving by alcohol dependent patients. Moreover, drug dependent patients are usually not restricted in driving possibility during drug free therapy.

The possibility to drive is an important element of quality of life, at least for several people. Quite often the possibility to driving make life much lighter, increase work capacity and can make it easier to reach the methadone distribution centre. This is one of the elements which expand life capabilities.

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# 6 Proposal for guiding principles in developing regulations concerning substitution treatment and driving

- The philosophy underlying the guiding principles should be to promote and support the ability to drive, which in today's world is crucial for social existence, for people with physical and medical handicaps alike.

- National laws and their enforcement need to strike a balance between concerns about ensuring road safety and the rights and therapeutic needs of individuals.

- The concept of non-discrimination and non-stigmatisation should be guiding the development of principles. Therefore the main criteria for limiting driving should be the influence of the substitution substance on the driving related skills of the patient .There should be no basic difference made between patients in substitution treatment and patients in other medicinal psychoactive treatments. The substance used for substitution (methadone or buprenorphine) and the dose given are not criteria for fitness to drive, with the exception of diamorphine. Adequate substitution treatment in terms of stabilizing the patient is much more important

- People on substitution therapy represent a comparatively small group of road users, thus excessive regulation does not seem appropriate.

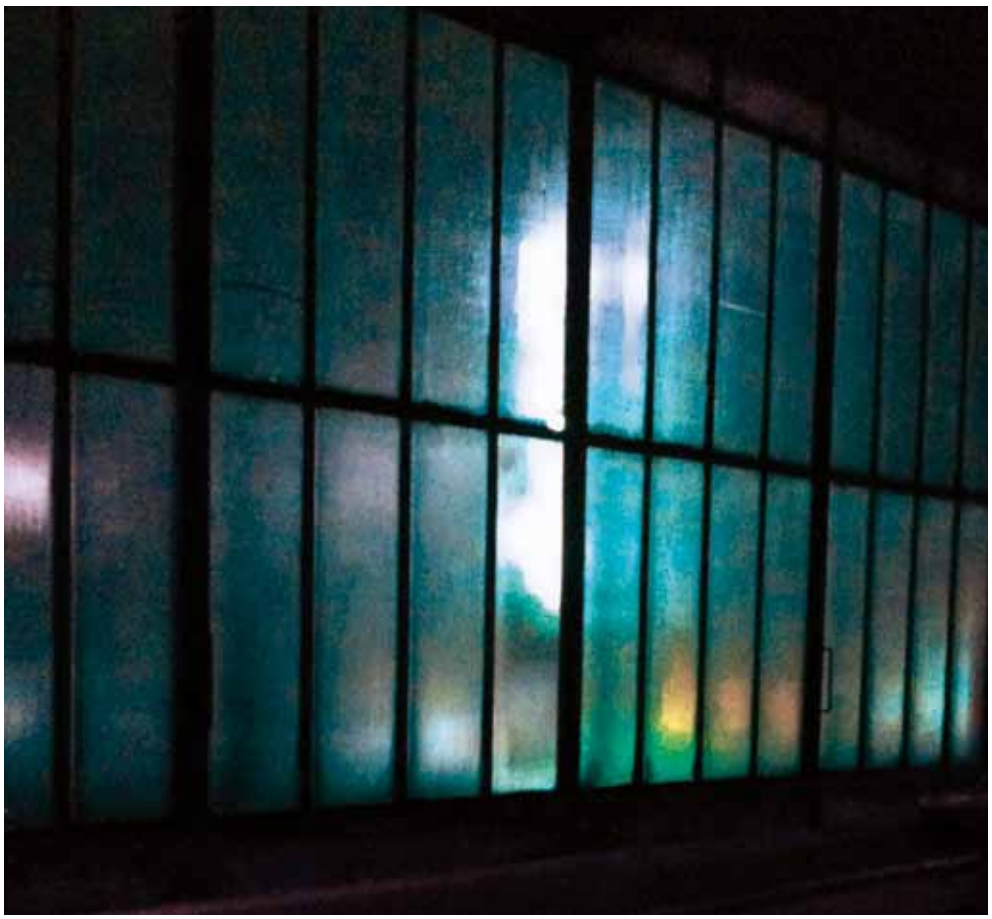
- The existing scientific literature up to date is too limited to draw clear conclusions regarding substitution medicines and driving ability. There is no strong evidence that patients in substitution treatment should not be allowed to drive.

- An early integration and the option of conditional license are important and support the rehabilitation progress. A model of conditional license with regular medical follow-up-controls concerning the ability to drive is recommendable. The development of a rigid assessment and evaluation model is inadequate. The model should be individually adaptable.

- Each patient in substitution therapy has to be regularly assessed regarding fitness to drive. Assessment of fitness to drive must always take into account circumstances considered as potentially capable to impair driving ability:
  - Any relevant co-morbidity
  - Any relevant co-medication
  - Other substance dependencies, in particular alcohol and benzodiazepine addiction
  - Other common mental health problems such as depression and anxiety
  - Somatic diseases such as diabetes, epilepsy, etc.
  - Any deviation from the treatment plan which involves missed doses, lapses and relapses, consumption of other drugs licit or illicit and readjustment of dosing.
  - Older patients (senior citizens) on long-term substitution therapy with additional relevant diseases, who are on medication, or who have age-related impairment of cognitive function, need special attention and must be carefully monitored.

- In the prime period of substitutions therapy, it is advisable to allow a period during which they are advised not to drive.

- Rules allowing a less restrictive monitoring are to be provided for patients on stable long-term substitution.
- Professional driving is an issue that has to be specially regulated. Cooperation with the occupational medicine service can be crucial for an adaptation of the work task.
- Diamorphine has different pharmacological properties than methadone and buprenorphine and requires the drug to be injected twice daily. Consequently patients treated with diamorphine need special attention.



# 7. Proposal for measures supporting the implementation of guiding principles

Because the “every day” decision to drive is the responsibility of each patient in substitution therapy, after receiving advice from his or her physician, (except when it has been said not to drive for example during a certain period of adaptation of therapy), two main actions must be promoted:

## 7.1 Training and information of health practitioners

- First of all, general practitioners, and physicians specialized in addictions, but also pharmacists who deliver substitution medicine, must be trained.
- Training and information with regards to the challenges of driving during substitution treatment should include the principles listed above, the legislation for each country and the importance of providing each patient with the information needed to make a realistic assessment of his or her ability to drive at any given moment
- This information is to be introduced in initial and continued training of professionals to adapt to the new evidence based knowledge and evolving legislation.

## 7.2 Information of population

- A system of graduated classification of psychoactive medicines into different classes is recommended. The level must be written on the packaging and an advice about driving delivered on the specification sheet. This informs the patient and makes him able to take his responsibility when the decision to drive is to be taken. An example is France, where a classifications system of three degrees is used: 1 - small effects on driving capacity, be careful; 2 - effects which can affect driving capacity, ask for a practionner advice; 3 - non compatible with driving, you must not drive. The classes are associated with a logo representing a car in a red triangle.
- Another helpful tool for the health worker could be given by a system of automatic entry of the classification of the medicine and cautions on the prescription by prescription software.
- Because of the very small group of population concerned, it is not adequate to make a communication campaign on this theme. It must be included in a larger campaign about caution to take with psychoactive substances and driving which is absolutely compulsory considering the high level of their consumption in Europe.
- Possessing and presenting a legal prescription of substitution medication might be useful in countries where there is road side detection of substitution medicines, but always in the context that there is no current impairment of the driving capability.

# 8. List of Participants

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