



Project No. TREN-05-FP6TR-S07.61320-518404-DRUID

DRUID
Driving under the Influence of Drugs, Alcohol and Medicines

Integrated Project
1.6. Sustainable Development, Global Change and Ecosystem
1.6.2: Sustainable Surface Transport

6th Framework Programme
Deliverable 7.2.1.

Recommendations for improving medical guidelines for assessing fitness to drive in patients who use psychotropic medicines

Due date of deliverable: (01.10.2009)
Actual submission date: (21.09.2009)

Start date of project: 15.10.2006
Duration: 48 months

Organisation name of lead contractor for this deliverable: RUGPha
Revision 2.0

Project co-funded by the European Commission within the Sixth Framework Programme (2002-2006)		
Dissemination Level		
PU	Public	X
PP	Restricted to other programme participants (including the Commission Services)	
RE	Restricted to a group specified by the consortium (including the Commission Services)	
CO	Confidential, only for members of the consortium (including the Commission Services)	

Task 7.2.1.

Recommendations for improving medical guidelines for assessing fitness to drive in patients who use psychotropic medicines

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Project funded by the European Commission under the Transport RTD Programme of the 6th Framework Program

Content

	PAGE
List of Tables	4
List of Abbreviations	5
Executive Summary	6
1. Introductory note	8
2. Questionnaire among driving licensing authorities	9
2.1. Introduction.....	9
2.2. Aim.....	12
2.3. Methods.....	13
2.4. Results.....	14
2.5. Discussion.....	28
2.6. Conclusion.....	29
2.7. Acknowledgements.....	30
Annex 1.....	31
Annex 2.....	35
3. Recommendations	57
3.1. Revising Art.15 in Council Directive 91/439/EEC.....	59
3.2. Application of the DRUID categorization system	63
3.3. Documentation of consultation.....	64

List of Tables

	Page
Table 1: Overview of experts responding to the questionnaire	30
Table 2: Proposed DRUID categorization system	58

List of Abbreviations

Abbreviation	Full Description
BAC	Blood Alcohol Concentration
BAST	Bundesanstalt für Strassenwesen
DGT	Dirección General de Tráfico
DRUID	Driving under the Influence of Drugs, Alcohol and Medicines
EEC	European Economic Community
ICADTS	International Council on Alcohol, Drugs and Traffic Safety
MDEA	Methylenedioxy-ethylamphetamine
MDMA	Methylenedioxy-methamphetamine
WHO	World Health Organization

Executive Summary

This Deliverable will report on the activities in Task 7.2.1. for evaluating the existing medical guidelines for assessing fitness to drive within the framework of Council Directive 91/439/EEC on driving licences. An overview of the current European regulations with respect to the assessment of fitness to drive and on driving performance in case patients use psychotropic medicines will be presented. A questionnaire survey among driving licensing authorities and experts was conducted in order to obtain better insights into the current situation in Europe concerning guidelines for physicians on prescribing medicines with impact on driving performance and on assessing fitness to drive. In addition existing guidelines for pharmacists on advising patients while dispensing those medicines were considered. Furthermore, it was decided to collect additional information on court cases in order to see if there could be a sufficient number of cases for evaluation of guidelines on the basis of legal outcomes in the event of accidents occurring after a positive decision from a physician's side.

Although the original title of D.7.2.1. suggests that proposals for implementing improvements in legislation and procedures for assessing fitness to drive) will be included in this Deliverable, it was made clear after several discussions that a proposal for improving such legislation will not be delivered, since this is not considered a task to be conducted by the WP 7 Partners. This was agreed by the DRUID Coordinator after consulting the European Commission. However, WP 7 Partners were requested to provide reflections on the possible ways how to improve the articles on medicines and substances other than alcohol in Council Directive 91/439/EEC.

Feedback on the questionnaire was received from 18 countries resulting in a response rate of 62%. Concerning prescribing and dispensing of psychotropic medicines, which might have an impact on the driving performance, it was concluded that strict and binding regulations are the exception rather than the rule. The compiled guidelines are typically recommendations not regulations. The role, responsibilities and tasks of physicians and pharmacists are not defined uniformly. Despite the great diversification of recommendations in the different countries one can deduct a common denominator. Physicians and pharmacists usually should give their patients the most comprehensive and adequate advice on medicines and their effect on driving performance. This includes not leaving the patient alone with the decision, how to decide whether or not to drive while using medicines.

In most cases physicians and pharmacists will not be made legally responsible in case an accident happens to one of their patients under a certain medication. But they are advised to keep a proper record of the consultation, as they might be sued in civil court cases (by insurance companies).

The regulations in the different countries dealing with the procedures of assessing fitness to drive are mainly in line with the Council Directive. Practical implementations and the assignment of responsibilities differ from country to country. It is very difficult to derive a "best practice" from the present results.

Following this survey it was felt impossible to obtain enough cases to evaluate the existing medical guidelines (for assessing fitness to drive) on the basis of legal outcomes in the event of accidents

In the last part of the Deliverable several opportunities to improve guidelines and procedures for assessing fitness to drive are presented based on the progress made within DRUID Workpackages 4 and 7. Several reflections on the existing guidelines and regulations, in particular on the text of Art 15. of Council Directive 91-439-EEC resulted in 8 recommendations.

Some of the recommendations point at the vague terms that are used in Article 15 (such as “substance abuse”, “regular use”, both for medicines and illicit drugs, etc.), whereas more internationally accepted terms exist. It is also recommended to include the underlying cause or reason for taking medicines, as well as all co-morbidity factors, while assessing fitness to drive. Another recommendation points at the term ‘combinations of medicines with central nervous system activity’. It is emphasized that combinations of psychotropic medicines with other medication that can alter the metabolism of the psychotropic medicine (with a possible consequence of increased blood levels of the latter) will always call for an individual judgement by the prescribing physician. This is especially of interest for drivers with co-morbidities and in case of polypharmacy.

It is also recommended to apply the DRUID categorization system for medicines affecting driving performance in developing national requirements for fitness to drive.

Finally it is recommended that in situations where physicians will advise a patient to start driving again after a period in which the advice was given not to drive while using the medicine, specific procedures are needed to structure the consultation and to manage the risk of litigation in case an accident could occur.

It will take special efforts to derive at consensus at a European level for the use of terms and procedures that allow improvements for assessing fitness to drive. Therefore it is recommended that working groups and expert rounds should discuss the proposed recommendations as presented in this deliverable with physicians, pharmacists, driving licensing authorities and policy makers.

1. Introductory note

During the discussions among WP 7 Partners on Deliverable D 7.2.1. (Report with a proposal for implementing improvements in legislation and procedures for assessing fitness to drive) it was made clear that WP 7 Partners will not deliver a proposal for improving legislation, since this is not considered a task to be conducted by the WP 7 Partners. However, WP 7 Partners will provide reflections on the possible ways how to improve the articles on medicines and substances other than alcohol in Council Directive 91/439/EEC. This was agreed in communications with the Coordinator and the Commission in March 2009.

In Annex I of the DRUID Core Contract it has been described that existing medical guidelines for assessing fitness to drive will be evaluated on the basis of legal outcomes in the event of accidents occurring after a positive decision from a physician's side. A proposal for improving procedures within those guidelines is expected to be presented as an outcome of task 7.2.

Partners in WP 7 have discussed existing guidelines for assessing fitness to drive and several recommendations will be presented in this Deliverable on how to improve present procedures.

First the results of a questionnaire survey among driving licensing authorities in European countries will be presented.

2. Questionnaire among driving licensing authorities

2.1. Introduction

To fulfil the objectives outlined in Annex-I (Description of Work within DRUID) the partners of Task 7.2 decided to present an overview of the current European regulations with respect to the assessment of fitness to drive and on driving performance in case patients use psychotropic medicines. In its most general sense, the term "psychotropic medicines" has the same meaning as "psychoactive medicines", i.e. affecting the mind or mental processes. In the context of this Deliverable the term will be applied to medicines whose primary use is in the treatment of mental disorders (anxiolytic sedatives, antidepressants, antimanic agents, and neuroleptics), and the treatment of sleep disorders (hypnotics). This terminology is based on the WHO lexicon of alcohol and drug terms (http://www.who.int/substance_abuse/terminology/who_lexicon/en/)

A questionnaire survey was conducted in order to obtain better insights into the current situation in Europe concerning guidelines for physicians on prescribing medicines with impact on driving performance and on assessing fitness to drive. In addition it was considered useful to include questions on existing guidelines for pharmacists on advising patients while dispensing those medicines. It was felt important to know whether and to what extent physicians take responsibilities in the process of assessing fitness to drive and whether efforts have been made to evaluate the current systems. Furthermore, it was decided to collect additional information on court cases in order to see if there could be a sufficient number of cases for evaluation of guidelines on the basis of legal outcomes in the event of accidents occurring after a positive decision from a physician's side.

The goals of Task 7.2 of the DRUID project are defined and described in a few basic documents relevant for DRUID - the original Call, respective chapters in Annex I of the core contract and the Council Directive 91/439/EEC. As background information for this Deliverable the relevant text passages are quoted below.

Call 3A

Task n°6

At the level of the doctors, propose procedures allowing them to exert a responsibility in the process of determining the fitness to drive of driving licence holders, without incurring possible penal proceedings in the event of accidents occurring after a positive decision from their side. These procedures fall within the framework of Council Directive 91/439/EEC on driving licences. Considered duration of this task: 2 years.

DRUID - Annex I

Objectives

Development of prescribing and dispensing guidelines for physicians and pharmacists to select the least impairing medicine within a therapeutic class and to provide patient information that will meet the patient's needs.

Proposal for improving the procedures for assessing fitness to drive within the framework of Council Directive 91/439/EEC (on driving licences), allowing doctors to exert a responsibility in this process without incurring possible penal proceedings in the event of an accident occurring after a positive decision from their side.

Task 7.2 Guidelines and professional standards

Based on the outcomes of Tasks 1.3 „Recommendation of thresholds“, Task 2.3 „Relative risk estimation“, Task 4.2 „Consensus“, Task 5.2 „Good practice“, Task 7.1 „State of the art“ and a close co-operation with Task 1.4 „Integration of results“, the scope and effectiveness of professional medical and pharmaceutical standards will be discussed with European organisations of physicians and pharmacists. Their reflections will be used as input for the development of a proposal to show how the prescribing and dispensing of medicines affecting driving performance can be guided by applying protocols. Specific attention will be given to the possibilities of using Information and Communication Technology (ICT) in the computerised information systems that physicians and pharmacists use in their daily practice. Specific attention will be given to the role of health care professionals in case psychoactive substances other than medicines will be used by their patients.

Based on the outcomes of Task 7.1. and the procedures within the framework of Council Directive 91/439/EEC (on driving licences) the existing medical guidelines for assessing fitness to drive will be evaluated on the basis of legal outcomes in the event of accidents occurring after a positive decision from a physician's side. After reviewing some best practices a proposal for implementing improvements in legislation and procedures will be presented.

COUNCIL DIRECTIVE of 29 July 1991 on driving licences (91/439/EEC)

Annex III

ALCOHOL

14. Alcohol consumption constitutes a major danger to road safety. In view of the scale of the problem, the medical profession must be very vigilant.

Group 1:

14.1. Driving licences shall not be issued to, or renewed for, applicants or drivers who are dependent on alcohol or unable to refrain from drinking and driving. After a proven period of abstinence and subject to authorized medical opinion and regular medical check-ups, driving licences may be issued to, or renewed for, applicant or drivers who have in the past been dependent on alcohol.

Group 2:

14.2. The competent medical authority shall give due consideration to the additional risks and dangers involved in the driving of vehicles covered by the definition of this group.

DRUGS AND MEDICINAL PRODUCTS

15. Abuse:

Driving licences shall not be issued to or renewed for applicants or drivers who are dependent on psychotropic substances or who are not dependent on such substances but regularly abuse them, whatever category of licence is requested.

Regular use:

Group 1:

15.1. Driving licences 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. This shall apply to all other medicinal products or combinations of medicinal products which affect the ability to drive.

Group 2:

15.2. The competent medical authority shall give due consideration to the additional risks and dangers involved in the driving of vehicles covered by the definitions of this group.

2.2. Aim of the questionnaire survey

The primary goal of the questionnaire survey was to obtain better insight into the current situation in Europe concerning medical guidelines on prescribing medicines with impact on driving performance of patients and on guidelines for assessing fitness to drive.

It was also the objective of the survey to compile information on “best practices” in order to derive recommendations on how to improve procedures and guidelines making use of the outcomes of the relevant parts of the entire DRUID-project.

2.3. Methods

A questionnaire was developed within Task 7.2, which consists of two parts with 10 major questions in total. The first part of the questionnaire deals with prescribing and dispensing of psychotropic medicines, the second part with assessing the fitness to drive of a patient who uses driving-impairing medicines. The questionnaire was sent out to experts in the field of developing medical guidelines for assessing fitness to drive and driving licensing authorities in 29 European countries (all EU member states, Switzerland, Norway).

The period of data collection was from September 2008 to November 2008.

2.4. Results

After two reminders and extending the deadline twice, we received feedback from 18 countries resulting in a response rate of 62%. The results of the questionnaire are presented as an extended summary. For more detailed information on the countries involved, please see Annex 2.

(Country abbreviations are given in small brackets.)

Part I. Prescribing and dispensing psychotropic medicines

Medical guidelines/procedures on prescribing or dispensing medicines

Most countries (11 out of 18 (B BUL CH D DK E F H N NL S)) state that they have some sort of medical guidelines/procedures on prescribing or dispensing medicines that might have impact on the driving performance. These guidelines are not always binding in the respective countries and show considerable differences in attributes and specifications. Some countries have introduced a system of warning labels on packages (e.g. France, Norway, Hungary).

In France the practitioners are recommended to choose the most appropriate medicine for their patients who drive. This is based on the national categorisation of medicinal drugs (4 categories). Physicians and pharmacists are encouraged to discuss with the patients their driving situation and their medical treatment.

In The Netherlands an advice was published in 1973 by the Royal Dutch Medical Organisation together with the Royal Dutch Pharmacy Organisation that all dispensed medicines with a negative effect on driving performance should have a warning sticker: a red sticker "Do not drive" or a yellow sticker "This medicine may influence your ability to drive". Nowadays some pharmacists still use yellow stickers, but also print the warning of the yellow sticker on the dispensing label with instructions for the patient how to use the medicine, affixed on the package. The red warning sticker is no longer in use, because physicians normally do not indicate its use on the prescription for informing the pharmacist.

In Spain the Spanish Traffic Directorate published guidelines (book, 250 pages) for the assessment of medical professionals about fitness to drive. The guidelines include a chapter about medicines.

In Norway medicines with an impairing effect on driving performance are marked with a red triangle. In addition a package insert is included for all such medicines with the respective warning. Medicines with a potentially increased accident risk have no red triangle, but the package insert contains a special warning of the potential risk.

In Germany the tasks of physicians/pharmacists are defined in the usual contract governing medical treatment. This includes the consultation by the physician or

pharmacist and their duty to inform the patient about possible side-effects of medicines. There are no additional regulations about medicines with impairing effects on driving performance.

In Hungary there is a special labelling for medicines. For all medicines and substances signed by two empty crosses the following regulations apply: only those practitioners can prescribe them who have permission from the authorities, all these substances and medicines are strictly registered in the pharmacies in the same way as illicit drugs and the dispensing of these medicines is allowed only by pharmacists.

Sweden has regulations telling that if the medicines prescribed constitute a traffic safety hazard this might be a hindrance to hold a license if the treatment goes on for a longer time.

Bulgaria has rigid legal provisions on prescribing and dispensing narcotic and psychotropic medicines, incl. such affecting the driving performance. These provisions concern medical doctors and pharmacists. In addition there is an explicit legal requirement for the patient information leaflet to contain a warning when the pharmaceutical product could affect the driving performance.

Long-term treatment

Long-term treatment with medicines that may have impairing effects on driving performance is more or less subject of special regulations in some of the countries (7 out of 18 (BUL D DK E I N S)). But in most cases the respective regulations refer rather to certain diseases than to the medicines themselves, e.g. special regulations for patients with epilepsy (without epileptic attacks for 2 years) or a mental disease.

In Italy there exist three inter-dependent regulations dealing with illnesses requiring psychotropic treatment (Road Act, its Regulation, and Annex II to the 5th Title of the Regulation). But the final decision on driving is made under the medical evaluation, which is not supported by any formal guidelines.

In Germany the long-term treatment with psychoactive substances is regulated in the Guidelines for expertises on driver's aptitude (Chapter 3.12.2). A decision has to be made individually. Despite the fact, that for some diseases an adequate medication is necessary to create the preconditions for driving at all, it still has to be assessed, whether the long-term therapy will lead to severe driving impairment.

In Denmark the medical practitioner is obliged to inform the patient that the medicine - especially in the first period - will cause drowsiness and enhance the accident risk and that there is an increased risk when drinking alcohol at the same time. But this again does not contradict the fact that the driver himself or herself is responsible for driving and may only drive, if she/he is capable to do so. The same is again explicitly stated by Finland. The physician's role is to help

patients to maintain their fitness to drive as long as possible by giving adequate treatment and advice.

Legal obligations for physicians and pharmacists

In 10 out of 18 countries (B BUL CZ D DK EST F H NL SK) the physician is legally obliged to inform a patient on the possible effects of the prescribed/dispensed medicines on the driving performance. This sometimes is part of the contract governing medical treatment between the physician and his patient, wherein it is stated, that the physician has to inform about all possible side-effects of any prescribed medicine, including possible effects on the driving performance. In the other countries the responsibility to get proper information lies with the patient, the physician is only advised to give support.

In only 4 out of 18 countries (DK EST FIN NL) the physician is literally obliged to keep records of the consultation. In the countries where the physician is not obliged to keep a record, this does not automatically imply that the physician is absolutely released from responsibilities. Failing to keep a proper record may leave the physician in an uncomfortable position in case a patient sues him/her after an accident has happened. In some countries the patient record will be used as evidence.

In eight countries (B CZ D DK F FIN H NL) there could be legal consequences for a physician, who failed to inform a patient properly on the possible effects of his medicines on the driving performance. In some countries it is possible that he might be declared liable in case the patient caused an accident. Usually this is the case, when the patient sues him. In Germany the burden of proof rests with the patient. As there often is no legal definition of “driving performance”, it is in some countries sufficient that the patient is generally informed about possible side effects of the medicines (vigilance, eyesight etc.). In Italy insurance companies offer coverage for such responsibility, and it is frequent that physicians pay for this kind of insurance.

Court cases

In most countries it is unknown whether there are noteworthy numbers of court cases, when a physician has been made liable in case an accident has happened after prescription of certain medicines. The reason for this might be that those court cases are rather seldom events and that there is no central registration system.

In three countries (D F H) the estimation of numbers was below 5 cases per year – far too few to serve as a base for evaluation.

One can therefore assume that it is very unlikely to get enough cases to evaluate the existing medical guidelines on the basis of legal outcomes in the event of accidents (as proposed in Annex I).

Informing the authorities

In 13 out of 18 countries (B CH D E EST F GR I LUX N NL S SK) a medical practitioner and/or pharmacist is not legally obliged to inform the authorities, when prescribing or dispensing medicines that might affect the driving performance. In two countries (BUL CZ) this becomes necessary, when prescribing certain medicines (like opioids). But this is not with regard to the driving performance.

Two countries (FIN H) give the answer that a physician has to inform the authorities, if the driver's health condition is such that he/she is not anymore fit to drive. But no information has to be given about the prescribed medicines.

Special regulations for certain psychotropic substances

In 11 out of 18 countries (BUL D DK EST F FIN GR H N NL S) there are special regulations for the medical treatment with certain psychotropic substances.

All of these countries have special regulations and programs for substitution therapy (e.g. substitution with methadone). This includes certain limitations that change during the course of a therapy (driving is not allowed during the first few months of a therapy or after a change of dose – the range spreads from 6 month to two years). The therapy is usually strictly controlled or will be performed in specialized centres only. In France the patient must apply for a medical examination by the medical commission of the driving licence administration.

In seven countries (BUL DK EST FIN GR H NL) special regulations exist for pain treatment with opioids.

In Denmark the medical practitioner must recommend a driving-break, if high doses are administered from the start of the treatment. Driving-break might not be needed if the treatment starts by small doses (general practice is a few weeks).

In The Netherlands driving under the influence of opioids is currently not allowed. But a new (upcoming) regulation will allow driving two weeks after the start of the treatment.

For prescription of methadone and opioids often special prescription forms are mandatory. In some countries (e.g. Germany) those forms can only be obtained after a central registration and a record has to be kept on the used forms.

Cannabis as a medication is not allowed in most of the countries, i.e. there are no special regulations for treatment.

Other Regulations

In Hungary there is a special labelling for medicines. For all medicines and substances signed by two empty crosses apply the following regulations: only those practitioners can prescribe them who have permission from the authorities,

all these substances and medicines are strictly registered in the pharmacies in the same way as illicit drugs and the dispensing of these medicines is allowed only by pharmacists

In The Netherlands The Royal Dutch Pharmacists Organisation (KNMP) has recently evaluated all literature and classified all medicines that might influence driving abilities, using the ICADTS classification (category I, II, III). (Remark: a similar classification system including a labelling system exists in France, but this was not foreseen as an answer to this question).

Evaluation efforts

With the exception of Italy, there have been no efforts to evaluate the impact of the above mentioned current regulations/guidelines on road traffic safety in any of the countries.

In Italy there was a study to evaluate the impact of the severe raise of the penalties of driving impaired by psychoactive substances, imposed by a Governmental Decree. That decree was issued just before the holiday season's travels (beginning of August 2007). Despite that severe increase, the expected effect did not come, and even a (small) raise of fatal accidents has been registered in comparison with the same period of the previous year.

Part II. Assessing the fitness to drive

Official medical guidelines for assessing the fitness to drive of persons who use psychotropic medicines regularly

In 11 out of 18 countries (B BUL CZ D DK E F FIN GR NL S) guidelines exist on assessing the fitness to drive of persons who use psychotropic medicines regularly:

The Belgian regulations are described in the Royal Decree 23/03/1998 - 2006.

In Bulgaria a psychological test is mandatory for persons, who have been deprived of their driving license due to consumption of alcohol or opiates, before they are allowed to drive again. The consumption of such substances should be proven by specially approved devices. It is, however, not specified that opiates should have been used on a regular basis. Stricter rules apply in case of professional drivers within the public transportation system.

Date of issue: Ordinance Nr. 36 on the requirements for psychological fitness and the procedures on conducting psycho tests, SG Nr. 46 of 6 June 2006, last amendment SG Nr. 36 of 4 May 2007; Ordinance Nr. 30 on the procedures for proving the consumption of alcohol or other opiates by drivers, SG Nr. 63 of 17 July 2001, last amendment SG Nr. 23 of 17 March 2006.

Editing institution/authority: Ordinance Nr. 36 - Ministry of Transport; Ordinance Nr. 30 – Ministries of Health, of Internal Affairs and of Justice

In Czech substance dependent persons should have at least 2 years of supervised abstinence. This is the precondition to regain a driving license.

In Denmark the medical practitioner must judge whether a patient will be capable of driving a vehicle in a safe way.

VEJ No. 38 - Vejledning om ordination af afhængighedsskabende lægemidler; Date of issue: 09.07.2008; Editing institution/authority: Ministry of Interior and Health, National Board of Health

In Finland for alcohol and drugs these issues are regulated generally in the guidelines of Ministry of Health and Social Affairs: Assessment of Dependence and fitness to drive. Sosiaali- ja terveystieteiden ministeriö: Päihderiippuvuuden arviointi ja ajokelpoisuus. Opas lääkäreille. Guidelines to physicians. STM, oppaita 1998:6, Helsinki 1998

In France there are no specific procedures for medicines. General driving fitness regulations and the chapter concerning medicinal drugs simply say that people cannot drive if “the dose or the type of medicinal drugs is not compatible with driving”. Special attention is also given to medicinal drugs leading to an addiction. Date of issue: 21 dec 2005; Editing institution/authority: ministry of transportation, decreete

In Germany these issues are regulated in the Guidelines for expertises on driver's aptitude (Date of issue: 2000; Editing institution/authority: BAST). Persons, who are dependent on psychoactive substances, are generally not

allowed to drive a car. This does not apply, if a psychoactive substance is properly used in medical long-term treatment of a disease. In this case it is always an individual decision. Expertises will only be conducted occurrence related – e.g. when issuing or renewing a driving license or circumstantial-related at the instance of the driving license authorities (e.g. after traffic offences, accidents, reporting of impairment).

In Greece a re-examination on health/mental condition (by physician) and driving skills (by driving instructor) will be conducted, only if the person is recognised by the authorities (circumstantially).

In The Netherlands the advice on whether to drive or not is given by the prescribing doctor and the pharmacist on the base of a categorisation in group I, II, or III (ICADTS categorisation).

Date of issue: October 2008. Editing institution/authority: Royal Dutch Pharmacists Organisation (KNMP)

In Spain the Spanish Traffic Directorate published guidelines (book with 250 pages) for the assessment of medical professionals about fitness to drive. Date of issue: 2004

Editing institution/authority: Spanish National Traffic Directorate (Dirección General de Tráfico, DGT)

In Sweden booked guidelines exist, published by the Swedish Road Administration. The guidelines are not officially binding. Editing institution/authority: Swedish Road Administration

In seven of the above countries the guidelines are embedded in the national traffic act (B, BG, CH CZ, DEN, F, GR)

Conditions, when a person using psychotropic substances regularly is considered fit to drive

In 9 out of 18 countries (BUL CH CZ D E F FIN I NL) a person, who regularly uses psychotropic substances with a possible impact on the driving performance, is considered fit to drive under certain conditions. In most cases it depends upon the decision of the physician or upon an agreement and the discussion between the patient and the physician. The proper use of psychoactive medicines may not be considered as contraindication for driving. Most of the given answers refer to situations, when a medicine was used properly.

In France the decision is made after medical examination by the commission for driving licences of the administration, if the driver informs the administration (not always the case), or if he has to be checked by the medical commission after accident, offence, request by the police forces

In Germany the patient alone makes the final decision on driving while under treatment with psychoactive substances. The patient bears the responsibility.

She/he is obliged to seek appropriate information, e.g. advice and consultation by a physician and/or a pharmacist.

In the Netherlands it depends upon the categorisation in group I, II or III. In case an applicant is using medicines within category III regularly, a driver is not considered fit to drive. However, there are exceptions, such as the regular use of antiepileptics. After one year seizure free use of medicines a person can be declared fit to drive.

Misuse and abuse of medicines

Misuse and abuse of medicines was only discussed in the answers from Spain and Switzerland:

In Spain, if the patient suffered from a dependence / abuse status, the fitness to drive has to be assessed in a rehabilitation measure (mandatory reporting fulfilled by a psychologist or a psychiatrist).

In Switzerland article 2, 2ter of the Traffic Rule Regulations (VRV) regulates that persons who can prove that they use certain substances (Cannabis, heroin/morphine, cocaine, amphetamine, methamphetamine, MDEA or MDMA) according to medical prescription their non-fitness to drive is not automatically assumed when the substance is detected.

The issues of regulations in case of misuse/abuse/dependency and of rehabilitation measures have been thoroughly discussed in DRUID Work-Package 5 (please see the respective Deliverables).

Legal regulation (traffic act) on the fitness to drive of persons who use psychotropic medicines regularly

In 11 countries (B BUL CH CZ D EST F I N NL S) national legal regulations (traffic act) exist on the fitness to drive of persons who use psychotropic medicines regularly, e.g. in long-term-treatment.

In Belgium the regulations are, that in case of addiction or abuse a person is not fit to drive. The same applies for people who regularly use of psychotropic medicines with a negative effect on driving performance, perception, mood, attention, psycho-motor abilities and judgement. Royal Decree 23/03/1998; Date of issue: 1998

In the Czech Republic these issues are put into in regulation No. 277/2004, which amends Act No.361/2000 Coll., on Traffic on Land Communications and on Amendments to Certain Acts (Road Traffic Act), as amended, and Act No. 200/1990 Coll., on Offences (Offences Act), as amended. Date of issue: 26. 4. 2004; Editing institution/authority: Parliament of the Czech Republic

In Estonia this is regulated in § 20. Prohibition on driving vehicles of the Traffic Act, which states that a driver shall not be in a state of intoxication. A state of intoxication is a state of health which is caused by the consumption of alcohol, narcotic drugs or psychotropic substances and which results in disturbed or changed bodily or mental functions and reactions. Date of issue: entered into force 1 February 2001; Editing institution/authority: legislative council, Ministry of Economy and Transportation

In France a driver is supposed to inform the driving licence administration if she/he takes a medical treatment supposed to impair driving, but they are mainly checked when there are certain other circumstances that demand a check by the medical commission.

Date of issue: 21 12 2005 Editing institution/authority: Ministry of Transport

In Germany these issues are regulated in the Driver's license regulation (Fahrerlaubnisverordnung (FEV) §13, §14; Date of issue: 2000; Editing institution/authority: Federal Ministry of Transport, Building and Urban Affairs). When issuing or renewing a driving license, a medical expertise is necessary for people, whose driving license had been withdrawn due to dependency (drugs or alcohol) or who had multiple traffic offences due to alcohol, for people who use psychoactive substances mentioned in the Narcotics Law (BtmG) or who misuse other psychoactive substances. In certain cases an expertise by a medical practitioner is not sufficient and the driving license authorities may order a medical-psychological examination (MPU).

In Italy driving under the influence of psychotropic medicines is forbidden if they are dangerous for driving. This is put down in the Law, in its Regulations and in Annex II, but the evaluation of this eventual danger is left to the medical doctor or to the medical Commission, without guide-lines for them.

Date of issue: Road Act N. 285, issued 30/04/1992, but updated many times, even during this last year 2008. A complete reform of that Act is under elaboration in the Parliament. Editing institution/authority: Government

The Dutch legislation on fitness to drive ("Regeling eisen geschiktheid 2000") is published by the Ministry of Transport. Chapter 10 of this Directive concerns medicines that may influence driving performance. If a type of medicine is classified in category III (ICADTS classification) then the person taking that medicine is considered unfit to drive.

Date of issue: may 18th 2000 (several times updated since then)

Editing institution/authority: Ministry of Transport.

Norway has an impairment law. The Norwegian Road Traffic Act says that it is not allowed to drive under the influence of alcohol (BAC limit 0.2 g/L) or other drugs (which means both illegal drugs and psychoactive medicines). Date of issue: 3.10.08;

Editing institution/authority: Norwegian Institute of Public Health

In Sweden the regulations state that there an evaluation of such medication's effects on traffic safety should be made, but nothing more has been specified. In very few cases cognitive testing could be done, but otherwise it is the assessment of the medical practitioner that counts. The physician at the

authorities could also make his own judgement from dosage and sometimes from risky traffic situations that came to his knowledge

The use of certain psychoactive substances (like narcotic legal drugs), which have been medically prescribed and in case the intake is regular and prolonged, as well as the prescribed use of Methadone or other surrogate preparations shall be examined from a traffic safety point of view. If the use is assessed as a traffic safety risk, there are grounds for denial of possession.

Date of issue: 2008-05-01

Editing institution/authority: Swedish Road Administration

Official medical guidelines or legal regulations on how to assess the fitness to drive of persons who are dependent or who regularly abuse psychotropic substances

In 14 out of 18 countries (B BUL CH CZ D DK EST F FIN H I NL S SK) official medical guidelines or legal regulations exist on how to assess the fitness to drive of persons who are dependent or who regularly abuse psychotropic substances.

Denmark has special regulations for certain medicines. For opioids driving a private vehicle (no paying passengers) is allowed. If the medicine is given by injections, it is recommended not to allow driving of private vehicles.

For people, who use benzodiazepines with a half-life > 10 hours, it is recommended not to allow driving of private vehicles.

For people, who use benzodiazepines with half-life < 10 hours, driving licence can only be issued for a period of one year.

In Hungary regular medical checking is compulsory for renewing of the driving licence. Alcohol and illicit drug dependency are exclusion criteria.

In Netherlands abuse of any psychotropic substance (alcohol, drugs, medications) means unfit to drive.

The Swedish regulations contain a whole chapter dealing with these issues, e.g. including regulations for a time period to verify a sober lifestyle by checking biomedical markers.

Conditions under which a person who was dependent to or who regularly abused psychotropic substances may be considered fit to drive again

In three countries (EST H SK) a person who was dependent to or who regularly abused psychotropic substances may under no conditions be considered fit to drive again.

Most of the other countries declare special conditions, under which a person is considered fit to drive again.

In Belgium one has to prove an abstinence of at least 6 months, followed by a medical decision (treating physician, evaluating physician). The validity of the

driving license is limited to maximal 3 years.

In the Czech Republic this depends on the decision of the patient's general practitioner. E.g. the proper use of antidepressant, antiepileptic or analgesic drugs may not be considered as contraindication in some persons.

The Danish regulation says that the medical practitioner is in charge of deciding if and for how long the patient is not allowed to drive. If the medical practitioner assumes that the patient will not observe these rules, then he must address the medical officer of health in order to find a solution.

In Luxembourg, Greece and Finland the people have to pass a medical assessment after the treatment.

In Germany a person has to undergo a medical-psychological Examination (MPU). This includes proving abstinence for a certain time period via biochemical tests (urine, blood). The final decision, whether a person is fit to drive again, is nevertheless made by the driving license authority.

In Spain rehabilitation has to be proved through a mandatory report fulfilled by a psychologist or a psychiatrist. This can be done the earliest after one year from the start of the rehabilitation program.

In Sweden one has to prove, that one has been without drug use for a time long enough, verified by urine testing. Everyone who is convicted of drunk driving with a BAC over 0.1 % should prove that he/she is not addicted.

Assessment approaches used to assess the fitness to drive

In six countries (DK EST FIN GR LUX NL) the assessment approach is solely a medical one, in one country (BUL) it is a psychological one. Seven countries (B CZ D E F H I) use a medical-psychological approach and in two countries this approach is complemented by a practical driving test.

In 9 countries (B CZ E F FIN GR H I S) the final decision on fitness to drive is a medical decision.

Two countries (CH D) state that the final decision lies with the authorities, i.e. not a medical or psychological decision. The results of the medical and psychological tests serve merely as input for the final decision.

Five countries (CZ D DK GR NL) use different approaches depending on the type of the category of offences (such as for example: alcohol offenders, drug offenders, young drivers, addicts, recidivists).

In the Czech Republic it depends on the circumstances and individual decision of general practitioners cooperating with other specialists.

Denmark has special regulations for drug addicts in substitution treatment.

In The Netherlands young offenders enter the procedure at lower BAC levels as well as recidivists.

Greece has special regulations for patients, using psychoactive substances. Patients are obliged to go through higher medical committee in state hospitals under the inspection of 5 clinic directors, who give the final medical result.

Even if the German approach (MPU) is obligatory for all offender groups, the MPU itself may differ in the methods according to the circumstances, e.g. drug tests for drug offenders, but no drug test for people with multiple traffic offences.

Legal consequences for medical practitioners

In most countries (14 out of 18 (BUL CH D DK E EST F FIN I LUX N NL S SK)) there will be no legal consequences for a medical practitioner, whose decision on fitness to drive led to granting or renewing a driving license and an accident happened afterwards, regardless of the causality of the accident. Usually the practitioner gives his judgement, but the final decision, whether a license is granted/renewed is made by the authorities. In some countries there is a possibility, that insurance companies might contradict the medical doctor's decision, or in case a related authority has any suspicion on fitness.

Noteworthy numbers of court cases are not known in any of the countries.

Court cases

Five countries (D E F H S) stated that noteworthy numbers do not exist of court cases, when the decision of a medical practitioner led to granting or renewing the driving license and an accident happened. In all other countries it was unknown, whether there are noteworthy numbers. The reason for this might be that those cases are rather seldom events and that there is no central registration routine.

One can therefore assume that it is very unlikely to get enough cases to evaluate the existing medical guidelines on the basis of legal outcomes in the event of accidents (as proposed in Annex I).

Evaluation efforts

Few efforts have been made in the different countries, to evaluate the impact of the guidelines on traffic safety, but the lack of these efforts is sometimes regretted.

Only three countries (FIN NL CH) can report efforts/studies to some extent:

Finland:

Päivi Rantanen, Mirja Mäkelä, Riitta Alaja, Kari Luotonen, Kaija Seppä.
Intoxicants and the driving licence. Helsinki, 2001, 69 p. (Reports of the Ministry of Social Affairs and Health, ISSN 1236-2115; 2001:8)

The aim of the project on intoxicants and the driving licence was to develop a practical model for referring drunken drivers to treatment. The background to making referrals is the endeavour to improve traffic safety. The objective is to reduce recurrences of drunken driving by assessing the drivers' road-worthiness and offering them help to control their use of intoxicants.

Referring drunken drivers to treatment is multi-professional co-operation. The police refer those found guilty of drunken driving to public health care or the special services of substance abuse clinics for an assessment of their dependency on intoxicants. The assessment takes from three to six months, and follow-up may continue after this. Control over the use of intoxicants is a prerequisite for permission to drive. This is monitored through comprehensive interviews and blood tests. The treatment aspect emerges from the client's situation. Drunken driving is frequently an indication of difficulties in mastery of one's own life and problems with substance abuse. In developing the treatment approach effort has been invested in taking account of how the individual referred for an assessment of intoxicant dependency can be supported and motivated while the assessment is in progress.

In 1999 and 2000 there were 255 clients having a driving licence assessment, 92 % of them men. Of those referred 80 % underwent assessment and 79 % of the assessments have progressed according to plan. Only a few negative statements have been written by doctors as some of those arriving for assessment dropped out of the programme before the statement was issued. Some 27 individuals participated in the assessment after driving under the influence of drugs. The programme has succeeded best in reaching people who are motivated to regain their driving licences and are able to make a commitment to a lengthy assessment period. The programme has been less successful in reaching those people with a severe substance dependency or a criminal history with drugs.

The experience of the project is that those referred for treatment have been reached more easily than anticipated. The attitudes among those coming in for assessment have been mostly positive. In the opinion of those conducting the assessment problems with substance use are brought under control more often than anticipated. The assessment is feasible within the present structures of social and health care, but undeniably requires more investment, which should guarantee resources primarily for primary health care and for special services for substance abuse at national level. Co-operation between the police and those conducting the assessments should be facilitated by legislation which makes information transfer easier.

The Netherlands:

A report by DHV Ruimte en Mobiliteit BV, dossier W 1539.01.001 (<http://parlis.nl/blg4269.pdf>) on the procedure mentioned above (2004: Evaluatie Vorderingsprocedure).

An educational course with the duration of 3 days will be mandatory for drivers with a high BAC of 1,3 – 1,8 g/L, if recidivism or a BAC higher than 1,8 g/L are detected medical evaluation by a psychiatrist will be needed for assessing fitness to drive. Based on statistical data about drink driving in the Netherlands and a literature review on the effectiveness of rehabilitation programs, estimations on the effectiveness of the Dutch procedures have been presented. This report states that the procedure of mandatory examination by a psychiatrist to determine substance abuse means a reduction of 27 fatalities per year. Furthermore several recommendations are presented to improve the procedures, such as better quality of data collected on alcohol use pattern, educational background and reason for apprehension by the police. Knowledge about these data will improve policies aimed at prevention. Better criteria for developing different target groups within the population of high BAC convicted drivers are recommended to improve alternative treatment measures such as alcoholock systems installed in the driver's car. The report concludes that the educational course and interventions by psychiatrists are cost-effective.

Switzerland:

Dubey Y, Gujer HR. [Alcohol intoxication at the wheel in the Waadt canton (Switzerland). A comparative study of penal and administrative measures 1970 and 1989 in the canton capital city (Lausanne) and a rural area] *Blutalkohol*. 1993 Sep; 30 (5):266-89. Germany.

The canton of Vaud is one of the major wine-growing areas of Switzerland. The driving ban rate for drunk driving is the highest in the country. This is the result of the very important rise in the number of drivers intercepted by the police for drunk driving (accidentless cases), in the course of the last ten years (+260%). In order to find out what penal and administrative measures were taken against drunk drivers (those who did not commit an accident), a comparative retrospective study of the offenses committed in the area of Lausanne and in rural area of the canton of Vaud (La Broye) was undertaken. This study deals with the years of 1970 and 1989. In a parallel, the average blood alcohol concentration (BAC) value, relative distribution of the BAC (frequency profile), and the concordance between the doctor's medical examination and the suspect's BAC were studied. Our results demonstrate that only the urban area (Lausanne) showed a significant increase in the drunk-driving offenses without accident, resulting in a significant decrease in the average BAC value as well as a veering towards the left of the BAC frequency profile curve. The legal sanctions and the administrative measures diverge according to the different areas, the most striking fact is the lowering of the average term of imprisonment for second-time or multiple offenders in the study group of Lausanne. The results of the clinical examination undertaken by the doctor at the moment of the blood test have shown that there is often a difference between the clinical evaluation and the actual BAC: for a BAC of 2 to 3/1000, the objective clinical symptoms of drunkenness (Romberg, unstable gait, coordination troubles) are noticed in only half of the cases. As a result, the assessment is no longer based on objective criteria but on subjective criteria as well as on the life-style of a certain period. In conclusion it is our belief that the efforts made by the Vaudois police (especially in urban areas) should be pursued further, since positive results are apparent. The Judiciary system should however rebalance the sanctions delivered to drunk-drivers, showing greater severity towards second-time or multiple offenders.

2.5. Discussion

Concerning prescribing and dispensing of psychotropic medicines, which might have an impact on the driving performance, strict and binding regulations are the exception rather than the rule. The compiled guidelines are typically recommendations not regulations. The role, responsibilities and tasks of physicians and pharmacists are not defined uniformly. Despite the great diversification of recommendations in the different countries one can deduct a common denominator. Physicians and pharmacists usually should give their patients the most comprehensive and adequate advice on medicines and their effect on driving performance. This includes not leaving the patient alone with the decision, how to decide whether or not to drive while using medicines.

In most cases physicians and pharmacists will not be made legally responsible in case an accident happens to one of their patients under a certain medication. But they are advised to keep a proper record of the consultation, as they might be sued in civil court cases (by insurance companies).

The regulations in the different countries dealing with the procedures of assessing fitness to drive are mainly in line with the Council Directive. Practical implementations and the assignment of responsibilities differ from country to country. It is very difficult to derive a “best practice” from the present results. However, given the outcomes of WP 4, where a categorization system for medicines affecting driving performance has been proposed, it is of interest to consider the use of these categories in defining fitness to drive. At least one country (the Netherlands) has enforced regulations to make use of such a categorization.

Following this survey it seems very unlikely to obtain enough cases to evaluate the existing medical guidelines (assessing fitness to drive) on the basis of legal outcomes in the event of accidents (as proposed in Annex I). Again it is impossible to define a “best practice” based on this limited information.

2.6. Conclusion

Although national guidelines seem to be in concordance with the Council Directive 91-439-EEC, it is not possible to retrieve the descriptions of terminology such as substances, regular use, etc. in a more comprehensive way. It will be more practical to use the descriptions according to internationally accepted terminologies such as used by the World Health Organisation.

Recommendations for common European guidelines could be drafted, partially integrating the results of this survey and the current regulations in Europe. It takes special efforts to derive at consensus at a European level, therefore it is expected that working groups and expert rounds should discuss the proposed recommendations with physicians, pharmacists, driving licensing authorities and policy makers.

2.7. Acknowledgments

The following experts from the governmental agencies and driving licensing authorities are gratefully acknowledged for their contributions in completing the questionnaire (Table 1).

Table 1: Overview of experts responding to the questionnaire

Country	Institute	Contact person
B	Ministry of Transport	Gilbert Auwaerts
BUL	National Transport Policy Directorate	Svetlana Spassova
CH	BfU	Stefan Siegchrist
CZ	CDV	Ales Zaoral
D	BAST	Michael Heiing
DK	DTU	Inger-Marie Bernhoft
E	DGT	Juan Carlos Luque
EST	Tallinn Transport Department	Harjo Andres
F	French Road Safety Council	Charles Mercier-Guyon
FIN	National Public Health Institute	Pirjo Lillsunde
GR	CERTH-HIT	Lila Gaitanadou
H	USZ	Lszl Institoris
I	SIPSiVi	Gian Marco Sardi
LUX	Ministry of Transport	Guy Heintz
N	Norwegian Institute of Public Health	Asbjorg Christophersen
NL	Centraal Bureau Rijvaardigheidsbewijzen	Ruud Bredewoud
S	Swedish Road Administration	Lars Englund
SK	Prezidium Policajného	Lubomir Durina

Annex 1



Questionnaire Form Task 7.2

Part I:

Medical guidelines on prescription of psychotropic medicines, that might affect driving performance

Part II:

Medical guidelines on assessing the fitness to drive of people who use psychotropic substances

Country:

Questionnaire completed by:

Name:
Fist name:
Institution:
Address:

Email address:
Telephone number:

Part I. Prescribing and dispensing psychotropic medicines

1. Are there any medical guidelines/procedures in your country on prescribing or dispensing medicines that might have an impact on the driving performance?

Yes No
If yes, please specify:

1.a Are there any special regulations for people who need a long-term treatment with such medicines?

Yes No
If yes, please specify:

2. Is a medical practitioner and/or pharmacist legally obliged to inform a patient on the possible effects of the prescribed/dispensed medicines on the driving performance?

Yes No (continue with question Nr. 3)

2.a Is he/she in any way obliged to keep record of the consultation?

Yes No

2.b If yes, are there any legal consequences for medical practitioners and/or pharmacists, who failed to inform a patient on the possible effects of his medication on the driving performance, in case the patient caused an accident?

Yes No

If yes, please specify:

2.c Do noteworthy numbers of court cases exist?

Yes No Don't know

If yes, please specify the number of cases (estimation of cases/year): _____

3. Is a medical practitioner and/or pharmacist legally obliged to inform the authorities, when prescribing or dispensing medicines that might affect the driving performance?

Yes Under certain circumstances No

If yes or only under certain circumstances, please specify:

4. Are there any special regulations for the medical treatment with certain psychotropic substances (e.g. drug-substitution, opioids, cannabis as medication)?

Yes No (continue with question Nr. 5)

4.a Substitution treatment:

Yes No

If yes, please specify:

4.b Pain treatment (opioids):

Yes No

If yes, please specify:

4.c Cannabis as medication:

Yes No

If yes, please specify:

4.d Others:

Yes No

If yes, please specify:

5. Have there ever been any efforts in your country to evaluate the impact of the above mentioned current regulations/guidelines on road traffic safety?

Yes No Don't know

If yes, please give a short description of the evaluation and the literature reference in case it has been published:

Part II. Assessing the fitness to drive

6. Are there any official medical guidelines in your country on how to assess the fitness to drive of persons who use psychotropic medicines regularly, e.g. in long-term-treatment?

Yes No

If yes, please, give a short description of the existing medical guidelines regarding the fitness to drive of persons who use psychotropic medicines regularly:

Date of issue:

Editing institution/authority:

6.a Are these guidelines legally embedded in your national traffic act?

Yes No

6.b Is a person who uses regularly psychotropic substances with a possible impact on the driving performance considered fit to drive under certain conditions?

Yes No

If yes, please specify the conditions:

7. Are there any national legal regulations (traffic act) on the fitness to drive of persons who use psychotropic medicines regularly, f.i. in long-term-treatment?

Yes No

7.a If yes, please, give a short description of the existing legal regulations regarding the fitness to drive of persons who use psychotropic medicines regularly (Reference):

Date of issue:

Editing institution/authority:

8. Are there any official medical guidelines or legal regulations in your country on how to assess the fitness to drive of persons who are dependent or who regularly abuse psychotropic substances?

Yes No

If yes, please specify:

8.a Is a person who was dependent to or who regularly abused psychotropic substances considered fit to drive again under certain conditions?

Yes No (continue with question Nr. 9)

If yes, please give a short description of the existing regulation/guidelines:

(f.i. does one look for medical problems in offenders; and when (1st time, second time or recidivists; based on BAC levels?); who decides (judge, legal framework)

8.b Which assessment approach(es) is(are) used to assess the fitness to drive? (Multiple answers are possible)

- Medical approach
- Psychological approach
- Others, please specify: _____

8.c In case several approaches are being used, is the final fitness to drive decision a medical decision?

Yes No

8.d Does the fitness to drive assessment procedure differ by offender group category (such as for example: alcohol offenders, drug offenders, young drivers, addicts, recidivists)?

Yes No

If yes, please specify the different offender group categories: _____

9. In case a medical practitioner is responsible for the final decision regarding the fitness to drive, are there legal consequences in case his/her decision led to granting or renewing the driving license and an accident happened?

Yes No

If yes, please specify:

9.a Do noteworthy numbers of court cases exist?

Yes No Don't know

If yes, please specify the number of cases (estimation of cases/year): _____

10. Have there ever been any efforts in your country to evaluate the impact of the current above mentioned regulations/guidelines regarding on traffic safety?

Yes No Don't know

If yes, please give a short description of the evaluation and the literature reference in case it has been published:

Thank you for your co-operation!

Annex 2

Responses provided by country

Part I. Prescribing and dispensing psychotropic medicines

1. Are there any medical guidelines/procedures in your country on prescribing or dispensing medicines that might have an impact on the driving performance?

Yes No
If yes, please specify:

Belgium	Yes	Royal Decree 23/03/1998
Bulgaria	Yes	There are rigid legal provisions on prescribing and dispensing narcotic and psychotropic medicaments, incl. such affecting the driving ability. These provisions concern medical doctors and pharmacists. In addition there is an explicit legal requirement for the PIL to contain warning, where the pharmaceutical product could affect the driving ability.
Czech	No	
Denmark	Yes	There exists a list of substances that are supposed to impair the driving abilities: http://www.laegemiddelstyrelsen.dk/1024/visLSArtikel.asp?artikelID=9058
Estonia	No	
Finland	No	But in the Book Pharmaca Phennica, that medical practioners are using, when prescribing medicaments, the information about impact on the driving ability is included. Those medicaments are marked by LH = dangerous for traffic. More detailed information about traffic safety issues in connection to these drugs is included as well.
France	Yes	Based on the categorisation of medicinal drugs, practitioners are recommended to choose the most convenient one for their patients who drive They are encouraged to discuss with their patients about their driving situation and their medical treatment
Germany	Yes	The usual contract governing medical treatment. Consultation by physician and pharmacist, duty to inform the patient about possible side-effects
Greece	No	
Hungary	Yes	Pharmindex
Italy	No	Nothing binding. Some Scientific Societies, for their associates, namely Psychiatrists, have produced some guidelines during specific congresses. These are more focused on the diagnosis than on the medicaments, which are mentioned by generic warnings, to be evaluated case by case.
Luxemburg	No	
Netherlands	Yes	In 1973 (adapted in 1983) the Royal Dutch Medical Organisation together with the Royal Dutch Pharmacy Organisation published an advice that all dispensed medicaments with a negative effect on driving ability should have a warning sticker. A red sticker "Do not drive" , or a yellow sticker "This medicament may influence your ability to drive" Nowadays pharmacists do not use stickers anymore but print the text on the box.
Norway	Yes	Such drugs are marked with a red triangle. In addition – a package insert

		is included for all such medicines with warning. For medicines with potential increased accident risk: They have no read triangle – but a package insert with warning of the potential risk -special for “new” users.
Slovakia	No	
Spain	Yes	A book-guideline (80 pages) edited by Valladolid University and the Spanish Traffic Directorate. Target of this book were general practitioners and pharmacists. Some brochure was made for specific people, like older people. Finally, a book (250 pages) was done by Spanish Traffic Directorate for the assessment of medical professionals about fitness to drive and for inform them in detail about Spanish rules in this matter. This book includes a chapter about medicines. Main References: - Del Río C, Álvarez FJ, González Luque JC. Guía de Prescripción Farmacológica y Seguridad Vial. Dirección General de Tráfico. Segunda edición. Madrid; 2002. - González Luque JC, Valdés Rodríguez E (Coordinadores). Manual de aspectos médicos relacionados con la capacidad para la conducción de vehículos. Dirección General de Tráfico. Segunda edición, Madrid; 2004.
Switzerland	Yes	Such medications can be prescribed by physicians, dentists, veterinarians and pharmacists.
Sweden	Yes	There are regulations telling that if the medicinal drugs prescribed constitute a traffic safety hazard thus might be a hindrance to hold a license if the treatment goes on for a longer time.

1.a Are there any special regulations for people who need a long-term treatment with such medicines?

Yes No

If yes, please specify:

Belgium	No	
Bulgaria	Yes	There is a National policy on mental health, covering people suffering from mental diseases. There is also a National programme on the development of a system of methadone-supporting programs.
Czech	No	
Denmark	Yes	By the start of the treatment, the medical practitioner must inform the patient that the medicine - especially in the first period - will cause drowsiness and enhance the accident risk and that there is a danger when drinking alcohol at the same time.
Estonia	No	
Finland	No	Driver is itself responsible for the driving and drives only if she/he is capable to do so. The physician helps patients to keep her/his driving ability as long as possible by giving treatment and advice.
France	No	
Germany	Yes	Guidelines for expertises on driver's aptitude
Greece	No	
Hungary	No	
Italy	Yes/No	This double X is not a mistake. Indeed, the illnesses requiring psychotropic treatment are foreseen in the three inter-dependent regulations (Road Act, its Regulation, and Annex II to the 5th Title of the Regulation), and explicitly excluded from drive if they could be dangerous, this statement being expressed in the subjunctive (hypothetic) case, that means,

		under the medical evaluation, not helped by any formal guidelines
Luxemburg	No	
Netherlands	No	
Norway	Yes	Patient with epilepsy – but this is also due to the diagnoses – they must have been with out epileptics attacks for 2 years before they can drive.
Slovakia	No	
Spain	Yes	
Switzerland	No	
Sweden	Yes	As above

2. Is a medical practitioner and/or pharmacist legally obliged to inform a patient on the possible effects of the prescribed/dispensed medicines on the driving performance?

Yes No (continue with question Nr. 3)

Belgium	Yes	
Bulgaria	Yes	
Czech	Yes	
Denmark	Yes	See above and the following: When prescribing, the medial practitioner must inform the patient that he should net be driving a car until after a habituation period. For some types of medicine, there exists a driving ban.
Estonia	Yes?	Obligations are general about the mandatory informing of patients. Medicinal Products Act (in Estonian language: Ravimiseadus) § 33 lg 5 Law of Obligations Act (in Estonian language: Võlaõigusseadus)
Finland	No	But they are advised to do so. Driver is itself responsible for the driving and drives only if she/he is capable to do so. The physician helps patients to keep her/his driving ability as long as possible by giving treatment and advice.
France	Yes	
Germany	Yes	
Greece	No	
Hungary	Yes	
Italy	No	
Luxemburg	No	
Netherlands	Yes	
Norway	No	but they are recommended to do it should do it
Slovakia	Yes	
Spain	No	
Switzerland	No	
Sweden	No	(Not formally, but this is often done anyway.)

2.a Is he/she in any way obliged to keep record of the consultation?

Yes No

Belgium	No	
Bulgaria	No	
Czech	No	
Denmark	Yes	
Estonia	Yes	Health Services Organisation Act Regulation No. 56 of the Minister of Social Affairs of 18 September 2008. The procedure and the conditions for the documentation of health services and storage of the documentation (in Estonian language: Tervishoiuteenuse osutamise dokumenteerimise ning nende dokumentide säilitamise tingimused ja kord, sotsiaalministri 18. septembri 2008. a määrus nr 56)
Finland	Yes	Patient records are kept
France	No	
Germany	No	(But in case the patient sues him/her after an accident, this would leave him in the position not to be made liable.)
Greece	No	
Hungary	No	
Italy	No	The big issue, in Italy, has been about which medical doctor had to take this responsibility: if it was the general practitioner, here called family-doctor, this professional could not avoid the allegation of awareness about the case-history. In order to get this responsibility, two different laws about the licensing procedure have foreseen the "anamnesic certificate", reporting the anamnesis, the case-history. But these two laws (the most recent being the law n. 85 of 2001) have never been implemented by a decree they had delegated for practical implementation. Therefore, the anamnesis is done by a medical doctor other than the one knowing the case-history. Practically, it becomes a self-declaration of the driver himself, while the doctor washes his hands as Pilatus.
Luxemburg	No	
Netherlands	Yes	
Norway	No	
Slovakia	No	
Spain	-	
Switzerland	-	
Sweden	-	

2.b If yes, are there any legal consequences for medical practitioners and/or pharmacists, who failed to inform a patient on the possible effects of his medication on the driving performance, in case the patient caused an accident?

Yes No

If yes, please specify:

Belgium	Yes	MD can be declared liable
Bulgaria	No	
Czech	Yes	Medical Practitioners should take all reasonable actions to ensure the patients they are treating a genuine medical condition and in case the treatment or prescribing may contribute to any serious side effects, practitioner is obliged to inform the patient. In spite of that obligation there is no legal definition that the medical practitioner has to mention „driving ability“ formulation (it is enough that the patient is generally informed about possible side effects on his vigilance)
Denmark	Yes	The National Board of Health might order the medical practitioner to keep records on his prescriptions of drug

		depending substances. If so, the records are submitted to the regional medical officer of health. If the medical practitioner does not comply with the demands, his right to prescribe (special types of) medicines might be withdrawn.
Estonia	No	
Finland	(No)	It could be, in accident cases
France	Yes	They can be prosecuted and punished in case of accident or if the patient sue them
Germany	Yes	In case the patient sues him after an accident, he can be made liable in case he did not follow his duty to inform the patient properly. The burden of proof rests with the patient.
Greece	No	
Hungary	Yes	If the medical practitioner fails to inform the patient there can be legal consequences
Italy	No	It is left to the professional's evaluation, with the limits shown above. Insurance companies offer coverage for such responsibility, and it is frequent that medical doctors pay for this kind of insurance.
Luxemburg	-	
Netherlands	Yes	
Norway	(-)	Some time the medical practitioners have to meet in court in cases of drugged driving where high concentrations of psychoactive medicines have been found in their blood samples. It has to be explained if the concentrations are according to the prescriptions.
Slovakia	No	
Spain	-	
Switzerland	-	
Sweden	-	

2.c Do noteworthy numbers of court cases exist?

Yes No Don't know

If yes, please specify the number of cases (estimation of cases/year): _____

Belgium	Don't know	
Bulgaria	Don't know	
Czech	Don't know	
Denmark	Don't know	
Estonia	Don't know	
Finland	Don't know	
France	Yes	<5 / year
Germany	No	<5 / year
Greece	Don't know	
Hungary	Yes	1-2/year
Italy	No/Don't know	We do not know, even after accurate search, of cases of punishment for doctors who failed to do so.
Luxemburg	Don't know	
Netherlands	No	
Norway		Norway has many drugged driving cases every year > 3000 where psychoactive medicines have been found in their blood samples – many of these cases end up in court bases on expert witness statement. However, in the majority of these cases (mainly those ending up in court) the blood concentrations are > therapeutic levels, a mixture of

		medicines, illegal drugs and/or alcohol, or a mixture of several psychoactive medicines (of at high blood conc) .
Slovakia	No	
Spain	-	
Switzerland	-	
Sweden	-	

3. Is a medical practitioner and/or pharmacist legally obliged to inform the authorities, when prescribing or dispensing medicines that might affect the driving performance?

Yes Under certain circumstances No

If yes or only under certain circumstances, please specify:

Belgium	No	
Bulgaria	Under certain circumstances	The Regional Centres for Health control the prescribing and dispensing of narcotic and psychotropic substances. It is not with regard to the driving ability.
Czech	Under certain circumstances	In case of prescribing or dispensing medicaments fall within opioids class, medical practitioner is obliged to make special record and pharmacist may dispense the medicaments only on special prescription (labelled with blue strip).
Denmark	Don't know	
Estonia	No	
Finland	Under certain circumstances	In general, the medical practitioner is obliged to inform the authorities if driver's health condition is such that he/she is not anymore fit to drive :73 a § (113/2004) in traffic law (267/1981) Publication: Ajoterveys ja tiedonkulku –työryhmän muistio. STM, työryhmämuistioita 2002:11
France	No	
Germany	No	
Greece	No	
Hungary	Under certain circumstances	The practitioner obliged to inform the authorities about the disease which affects the driving ability and not about the medicine
Italy	No	No, until the implementation of law 85/2001 will be done by the delegated decree.
Luxemburg	No	
Netherlands	No	
Norway	No	
Slovakia	No	
Spain	No	
Switzerland	No	According to article 14 of the traffic law (SVG) a physician can report drivers that are not able to drive safely to the authorities.
Sweden	No	

4. Are there any special regulations for the medical treatment with certain psychotropic substances (e.g. drug-substitution, opioids, cannabis as medication)?

Yes No (continue with question Nr. 5)

Belgium	No	
Bulgaria	Yes	
Czech	No	
Denmark	Yes	
Estonia	Yes	Narcotic Drugs and Psychotropic Substances Act (in Estonian language: Narkootiliste ja psühhotroopsete ainete ning nende lähteainete seadus)
Finland	Yes	
France	Yes	
Germany	Yes	
Greece	Yes	
Hungary	Yes	
Italy	No	
Luxemburg	No	
Netherlands	Yes	
Norway	Yes	
Slovakia	No	
Spain	No	
Switzerland	No	
Sweden	Yes	

4.a Substitution treatment:

Yes No

If yes, please specify:

Belgium	-	
Bulgaria	Yes	The Methadone-supporting programme as a substitution programme, is controlled by the Ministry of Health – secondary by-law
Czech	No	
Denmark	Yes	Metadon, up to 120 mg: It is recommended only to allow a driving licence for one year (all categories of vehicles only busses and taxies without paying passengers) Reference: VEJ NO. 42 http://www.sst.dk/publ/Publ2008/EFT/Narkotika/vejledning_stofmisbrugere_juli2008.pdf
Estonia	Yes	Practice Guidelines
Finland	Yes	special prescription form for controlled drugs
France	Yes	The patient must apply for a medical examination by the medical commission of the driving licence administration
Germany	Yes	To be found in the “Guidelines for expertises on driver’s aptitude”, Driver’s license regulation (Fahrerlaubnisverordnung (FEV))
Greece	Yes	Performed only in specialised centres
Hungary	Yes	
Italy	No	
Luxemburg	-	
Netherlands	No	
Norway	Yes	Patients on methadone or Subutex treatment cannot drive for the first 6 months after start treatment – if the doses are changed it is 6 new months. In addition, no use of

		other drugs must be documented (urine sample)
Slovakia	-	
Spain	-	
Switzerland	-	
Sweden	Yes	If by substitution treatment you mean like treating addiction to narcotics with for example Methadon we have a regulisation on licensing stating that you should be on such a treatment at least for 2 years before you can get your license back if you are diagnosed with a dependency of narcotics.

4.b Pain treatment (opioids):

Yes No

If yes, please specify:

Belgium	-	
Bulgaria	Yes	Provisions are contained in the Law on control over narcotic substances and the implementing regulations.
Czech	No	
Denmark	Yes	The medical practitioner must recommend a driving-break if high doses are administered from the start of the treatment. Driving-break might not be needed if the treatment starts by small doses. General praxis: A few weeks driving-break. Reference: VEJ No. 38 https://www.retsinformation.dk/Forms/R0900.aspx?s21=vejledning+om+ordination+af+afh%c3%a6ngighedsskabende+!%c3%a6gemidler&s20=2008&s22=%7c10%7c
Estonia	Yes	Practice Guidelines
Finland	Yes	special prescription form for controlled drugs, e.g. for morphine
France	No	
Germany	No	
Greece	Yes	Opioids are used only with special medical papers
Hungary	Yes	
Italy	No	
Luxemburg	-	
Netherlands	Yes	No driving allowed at the moment. This is going to change in a few weeks. New regulation will allow opiodes two weeks after the start of the treatment
Norway	No	
Slovakia	-	
Spain	-	
Switzerland	-	
Sweden	No	

4.c Cannabis as medication:

Yes No

If yes, please specify:

Belgium	-	
Bulgaria	No	
Czech	No	
Denmark	Don't know	
Estonia	No	As other drugs also Cannabis is illegal drug in Estonia
Finland	-	Not allowed to use normally. Only in certain special cases and needs special allowance

France	No	
Germany	No	
Greece	No	
Hungary	No	
Italy	No	
Luxemburg	-	
Netherlands	No	
Norway	-	
Slovakia	-	
Spain	-	
Switzerland	-	
Sweden	No	Such treatment is not possible in Sweden

4.d Others:

Yes No

If yes, please specify:

Belgium	-	
Bulgaria	-	
Czech	No	
Denmark	Don't know	
Estonia	Yes	Practice guidelines on treatment of narcomania
Finland	No	
France	No	
Germany	No	
Greece	No	
Hungary	Yes	For all medicines and substances signed by two empty cross: only those practitioners can prescribe them who have permission from the authorities all these substances and medicaments are strictly registered in the pharmacies in the same way as illicit drugs the expedition of these medicines is allowed only by graduated pharmacists
Italy	No	
Luxemburg	-	
Netherlands	Yes	The Royal Dutch Pharmacists Organisation (KNMP) has recently evaluated all literature and classified all medication that may influence driving abilities, using the ICADTS classification (category I, II, III).
Norway	-	
Slovakia	-	
Spain	-	
Switzerland	-	
Sweden	No	

5. Have there ever been any efforts in your country to evaluate the impact of the above mentioned current regulations/guidelines on road traffic safety?

Yes No Don't know

If yes, please give a short description of the evaluation and the literature reference in case it has been published:

Belgium	No	
Bulgaria	Don't know	
Czech	No	
Denmark	Don't know	
Estonia	No	
Finland	Don't know	
France	No	
Germany	No	
Greece	No	
Hungary	No	
Italy	Yes	The ACI, Italian Automobile Club, for the CNEL, the Italian Economic and Social Committee, in order to influence the elaboration of the new Road Regulations, tried to evaluate the impact of the severe raise of the punishments of drive impaired by these substances, imposed by a Governmental Decree. That decree was issued just before the holiday season's travels (beginning of August 2007). Despite that severe raise, the expected effect did not come, and even a (small) raise of fatal accidents has been registered in comparison with the same period of the previous year. The study suggested that a more clear definition and a more certain implementation of the Law should be more important than the theoretical raise of punishments. In practice, the only positive effect had been obtained in that period by the introduction of section-average-speed-controls in motorways, considered a best practice also by the SUPREME survey.
Luxemburg	No	
Netherlands	No	
Norway	No	
Slovakia	Don't know	
Spain	No	
Switzerland	No	
Sweden	No	

Part II. Assessing the fitness to drive

6. Are there any official medical guidelines in your country on how to assess the fitness to drive of persons who use psychotropic medicines regularly, f.i. in long-term-treatment?

Yes No

If yes, please, give a short description of the existing medical guidelines regarding the fitness to drive of persons who use psychotropic medicines regularly:

Date of issue:

Editing institution/authority:

Belgium	Yes	Described in Royal Decree 23/03/1998 - 2006 government
Bulgaria	Yes	<p>Where a person has been deprived of his driving license due to consumption of alcohol or opiates, the legislation provides for a psychological test before he is allowed to drive again. The consumption of such substances should be proven by specially approved devices. It is, however, not specified that opiates should have been used on a regular basis.</p> <p>Stricter rules apply in case of professional drivers for the public transport. Please, contact the Ministry of Transport for further information.</p> <p>Date of issue: Ordinance Nr. 36 on the requirements for psychological fitness and the procedures on conducting psycho tests, SG Nr. 46 of 6 June 2006, last amendment SG Nr. 36 of 4 May 2007; Ordinance Nr. 30 on the procedures for proving the consumption of alcohol or other opiates by drivers, SG Nr. 63 of 17 July 2001, last amendment SG Nr. 23 of 17 March 2006.</p> <p>Editing institution/authority: Ordinance Nr. 36 - Ministry of Transport; Ordinance Nr. 30 – Ministries of Health, of Internal Affairs and of Justice</p>
Czech	Yes	Substance dependent persons should have at least 2 years of supervised abstinence as the precondition to have a driving license.
Denmark	Yes	<p>The medical practitioner must judge whether a patient will be capable of driving a vehicle in a safe way.</p> <p>VEJ No. 38 Vejledning om ordination af afhængighedsskabende lægemidler https://www.retsinformation.dk/Forms/R0900.aspx?s21=vejledning+om+ordination+af+afh%c3%a6ngighedsskabende+%c3%a6gemidler&s20=2008&s22=%7c10%7c Date of issue: 09.07.2008 Editing institution/authority: Ministry of Interior and Health, National Board of Health</p>
Estonia	No	
Finland	Yes	<p>Generally for alcohol and drugs: The guidelines of Ministry of Health and Social Affairs : (Päihderiippuvuuden arviointi ja ajokelpoisuus =) Assessment of Dependence and fitness to drive. Sosiaali- ja terveystieteiden tutkimuskeskus: Päihderiippuvuuden arviointi ja ajokelpoisuus. Opas lääkäreille. Guidelines to physicians. STM, oppaita 1998:6, Helsinki 1998</p>
France	Yes	They are no specific procedure for medicines, they are general driving fitness regulations and the chapter concerning medicinal drugs simply says that people cannot drive if “ the dose or the type of medicinal drugs

		is not compatible with driving” a special attention is also given to medicinal drugs leading to an addiction Date of issue: 21 dec 2005 Editing institution/authority: ministry of transportation , decrete
Germany	Yes	Guidelines for expertises on driver's aptitude. Date of issue: 2000 Editing institution/authority: BAST
Greece	Yes	Yes but only if the person is recognised by the authorities (circumstantially). There is re-examination on health mental condition (by doctor) and driving skills (by driving examiner)
Hungary	No	
Italy	No	No, as described before: not official, only internal to the associates to private Scientific Societies, and not detailed on the treatment, but only on the diagnosis.
Luxemburg	No	
Netherlands	Yes	Advice on whether to drive or not is given by the prescribing doctor and the pharmacist on the base of a categorisation in group I, II, or III (ICADTS categorisation) Date of issue: October 2008. Editing institution/authority: Royal Dutch Pharmacists Organisation (KNMP)
Norway	No	
Slovakia	No	
Spain	Yes	See answer 1. Date of issue: 2004 Editing institution/authority: Spanish National Traffic Directorate (Dirección General de Tráfico, DGT). See referentes in answer 1
Switzerland	No	No official medical guideline, but a handbook of traffic medicine diagnostics (Handbuch der verkehrsmedizinischen Begutachtung)
Sweden	Yes	We have a book of guidelines published by the Swedish Road Administration and these questions are included here, but this book is not officially guidelines. Date of issue: 2008-05-01 Editing institution/authority :Swedish Road Administration

6.a Are these guidelines legally embedded in your national traffic act?

Yes No

Belgium	Yes	
Bulgaria	Yes	Both ordinances are based on the Traffic act.
Czech	Yes	
Denmark	Yes	
Estonia	No	
Finland	No	
France	Yes	
Germany	No	
Greece	Yes	
Hungary	-	
Italy	No	No. But the Italian Senate, during the elaboration of the new Road Act, still in course, has foreseen such guidelines to be issued and to be binding.
Luxemburg	-	
Netherlands	No	
Norway	-	
Slovakia	No	
Spain	No	
Switzerland	Yes	
Sweden	No	

6.b Is a person who uses regularly psychotropic substances with a possible impact on the driving performance considered fit to drive under certain conditions?

Yes No

If yes, please specify the conditions:

Belgium	No	
Bulgaria	Yes	<i>See above.</i>
Czech	Yes	It depends on the decision of his general practitioners. E.g. the proper use of antidepressant, antiepileptic or analgesic drugs may not be considered as contraindication in some persons.
Denmark		It is up to the medical doctor to decide.
Estonia	No	
Finland	Yes	the patients discuss with the doctor and the doctor gives advice
France	Yes	After medical examination by the commission for driving licences of the administration, if the drivers informs the administration (not always the case), or if he has to be checked by the medical commission after accident, offence, request of the police forces
Germany	Yes	Patient makes the final decision, whether he/she is fit to drive. She/he alone bears the responsibility. She/he is obliged to seek appropriate information, f.i. advice and consultation by physician and/or pharmacist.
Greece	No	
Hungary	-	
Italy	Yes	Agreed between the medical doctor and the patient. Even the private guidelines mentioned above are rather smooth in foreseeing just limitations on the time (e.g. control after two years) and in the degree of the licence (e.g., not professional, not heavy trucks etc.)
Luxemburg	No	
Netherlands	Yes	Depending on the categorisation in group I, II or III.
Norway	No	
Slovakia	No	
Spain	Yes	If the driver doesn't suffer from a dependence / abuse status, and if he / she does, rehabilitation have to be prove through a mandatory reporting fulfilled by a psychologist or a psychiatrist
Switzerland	Yes	In article 2, 2ter of the Traffic Rule Regulations (VRV) it is said that persons that can prove that they use certain substances (Cannabis, heroine/morphine, cocaine, amphetamine, methamphetamine, MDEA or MDMA) according to medical prescription the non-fitness to drive is not automatically assumed when the substance is detected. (Original: Für Personen, die nachweisen können, dass sie eine oder mehrere der in Absatz 2 aufgeführten Substanzen gemäss ärztlicher Verschreibung einnehmen, gilt Fahrunfähigkeit nicht bereits beim Nachweis einer Substanz nach Absatz 2 als erwiesen)
Sweden	No	

7. Are there any national legal regulations (traffic act) on the fitness to drive of persons who use psychotropic medicines regularly, f.i. in long-term-treatment?

Yes No

Belgium	Yes	
Bulgaria	Yes	See above.
Czech	Yes	
Denmark	No	
Estonia	Yes	
Finland	No	
France	Yes	
Germany	Yes	
Greece	No	
Hungary	No	
Italy	Yes	
Luxemburg	No	
Netherlands	Yes	
Norway	Yes	
Slovakia	No	
Spain	No	
Switzerland	Yes	
Sweden	Yes	The regulations state that there should be made an evaluation of such medication's effects on traffic safety, but nothing more specified. In very few cases cognitive testing could be done, but otherwise it is the assessment of the clinician that counts. The physician at the authorities could also make his own judgement from dosage and sometimes from risky traffic situations that came to his knowledge.

7.a If yes, please, give a short description of the existing legal regulations regarding the fitness to drive of persons who use psychotropic medicines regularly (Reference):

Date of issue:

Editing institution/authority:

Belgium		addiction or abuse: not fit to drive regular use and negative effect on driving ability: not fit to drive medicaments with negative effect on perception, mood, attention, psycho-motor abilities and judgement: not fit to drive Date of issue: 1998 gouvernement
Bulgaria		See above.
Czech		Implementing regulation No. 277/2004, which amends Act No.361/2000 Coll., on Traffic on Land Communications and on Amendments to Certain Acts (Road Traffic Act), as amended, and Act No. 200/1990 Coll., on Offences (Offences Act), as amended, called also a "Little Amendment". That has corrected the most significant mistakes of the Act No. 361/2000 Coll., on Road Traffic, as amended. Date of issue: 26. 4. 2004 Editing institution/authority: Parliament of the Czech Republic
Denmark	-	-
Estonia	Yes	Traffic Act (Law)

		<p>§ 20. Prohibition on driving vehicles</p> <p>(3) A driver shall not be in a state of intoxication. A state of intoxication is a state of health which is caused by the consumption of alcohol, narcotic drugs or psychotropic substances and which results in disturbed or changed bodily or mental functions and reactions.</p> <p>Date of issue: entered into force 1 February 2001 Editing institution/authority: legislative council, Ministry of Economy and Transportation</p>
Finland	-	
France		<p>Same situation as previous question: a driver is supposed to inform the driving licence administration if he takes a medical treatment supposed to impair driving, but they are mainly checked when they have another reason to be checked by the medical commission</p> <p>Date of issue: 21 12 2005 Editing institution/authority: ministry of transport (see attachment)</p>
Germany		<p>Driver's license regulation (Fahrerlaubnisverordnung (FEV))</p> <p>Date of issue: 2000 Editing institution/authority: Federal Ministry of Transport, Building and Urban Affairs</p>
Greece		<p>There are under the general law of testing driving ability after the treatment</p>
Hungary		-
Italy		<p>The use of psychotropic medicaments is foreseen, and forbidden if dangerous for the drive, in the Law, in its Regulations and it is Annex II, but the evaluation of this eventual danger is left to the medical doctor or to the medical Commission, without guide-lines for them.</p> <p>Date of issue: Road Act N. 285, issued 30/04/1992, but updated many times, even during this last year 2008. A complete reform of that Act is under elaboration in the Parliament.</p> <p>Editing institution/authority: the Government, delegated by the Parliament, so having the level of Law</p>
Luxemburg		-
Netherlands		<p>The Dutch legislation on fitness to drive ("Regeling eisen geschiktheid 2000") is published by the Ministry of Transport. Chapter 10 of this Directive concerns medication that may influence fitness to drive. If a type of medication is classified in category III (ICADTS classification) then the person taking that medication is considered unfit to drive.</p> <p>Date of issue: may 18th 2000 (several times updated since then) Editing institution/authority: Ministry of Transport.</p>
Norway		<p>Norway has an impairment law. The Norwegian Road Traffic Act says that it is not allowed to drive under the influence of alcohol (BAC limit 0,2 o/o) or other drugs (which means both illegal drugs and psychoactive medicines). Every year approx 4500 drivers are arrested for suspicion of driving under the influence of illegal or psychoactive drugs. In approx. 80% of the blood samples collected from the drivers one or more substances were detected in blood. (No of drivers suspicion of alcohol only: 5200 – 5500)</p> <p>Date of issue: 3.10.08 Editing institution/authority: Asbjørg S. Christophersen, Norwegian Institute of Public Health</p>
Slovakia		-
Spain		-
Switzerland		See question 6b
Sweden		The wording is approximately like this: "The use of substances provided in Section 1 (like narcotic legal drugs) which has been

		<p>medically prescribed which is regular and prolonged, as well as the prescribed use of Metadon or other surrogate preparations shall be examined from a traffic safety point of view. If the use is assessed as a traffic safety risk, there are grounds for denial of possession.</p> <p>Date of issue: 2008-05-01</p> <p>Editing institution/authority: Swedish Road Administration</p>
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8. Are there any official medical guidelines or legal regulations in your country on how to assess the fitness to drive of persons who are dependent or who regularly abuse psychotropic substances?

Yes No
 If yes, please specify:

Belgium	Yes	RD 23/03/1998
Bulgaria	Yes	See above.
Czech	Yes	Implementing regulation No. 277/2004, which amends Act No.361/2000 Coll.
Denmark	Yes	<p>Opioids below the max. DD, see enclosure 1: Driving a private vehicle (no paying passengers) is allowed</p> <p>If the medicine is given by injections, it is recommended not to allow driving of private vehicles.</p> <p>https://www.retsinformation.dk/Forms/R0900.aspx?s21=vejledning+om+ordination+af+afh%c3%a6ngighedsskabende+l%c3%a6gemidler&s20=2008&s22=%7c10%7c</p> <p>Benzo: For substances with half-life > 10 hours, it is recommended not to allow driving of private vehicles.</p> <p>For substances with half-life < 10 hours, driving licence can only be issued for a period of one year.</p>
Estonia	Yes	Regulation No. 257 of the Minister of Social Affairs of 29 September 2005. The requirements for the state of health of drivers of power-driven vehicles (in Estonian language: Mootorsõidukijuhi, trammijuhi ja juhtimisõiguse taotleja tervisenõuded, eelneva ja perioodilise tervisekontrolli tingimused ja kord ning tervisetõendite vormid, Vabariigi Valitsuse 29. septembri 2005. a määrus nr 257)
Finland	Yes	<p>The guidelines of Ministry of Health and Social Affairs : (Päihderippuvuuden arviointi ja ajokelpoisuus =) Assessment of Dependence and fitness to drive</p> <p>Päivi Rantanen, Mirja Mäkelä, Riitta Alaja, Kari Luotonen, Kaija Seppä : Intoxicants and the driving licence. Helsinki 2001, 69 p. (Reports of the Ministry of Social Affairs and Health, ISSN 1236-2115;2001:8, ISBN 952-===-1016-5</p>
France	Yes	Same as previous question
Germany	Yes	Guidelines for expertises on driver's aptitude (see above)
Greece	No	but there are regulations for flying
Hungary	Yes	Regular medical checking is compulsory for renewing driving licence. Alcohol and illicit drug dependency are exclusion criteria.
Italy	Yes/no	<p>When a doubt raises, the competence to decide is devoted to a Medical Commission, foreseen by article 119 of the Road Act (Codice della Strada).</p> <p>Here we have the same question above described about the medicaments. The health operators who really know the matter are in the SERT, the public services for drug addicts. But the law regulating</p>

		these services explicitly make them free from the obligation to report on the behaviour of their assisted persons, recalling a more general article 365 of our "Codice Penale", Criminal Code, which explicitly exclude the obligation to report on crimes the health operator has known while assisting his patient. The health operator is not only the medical doctor, but also the psychologist, the nurse and so on. There are frequent discussions about this issue, but so far the legal situation is this one.
Luxemburg	No	
Netherlands	Yes	Abuse of any psychotropic substance (alcohol, drugs, medications) means unfit to drive.
Norway	No	
Slovakia	Yes	Act./2008 Z.z. about road traffic in the last wording (will be valid from 1.2.2009)
Spain	No	
Switzerland	Yes	Directive on the ascertainment of unfitness to drive from the 1 st of September 2004 (Original: Weisungen betreffend die Feststellung der Fahrunfähigkeit im Strassenverkehr)
Sweden	Yes	There is a whole chapter on this in the regulations about driver fitness including enough long time to verify a sober lifestyle by checking biomedical markers.

8.a Is a person who was dependent to or who regularly abused psychotropic substances considered fit to drive again under certain conditions?

Yes No (continue with question Nr. 9)

If yes, please give a short description of the existing regulation/guidelines:

(f.i. does one look for medical problems in offenders; and when (1st time, second time or recidivists; based on BAC levels?); who decides (judge, legal framework)

Belgium	Yes	proven abstinence of at least 6 months validity of max 3 years medical decision (treating physician, evaluating physician)
Bulgaria	Yes	See above.
Czech	Yes	It depends on the decision of his general practitioners. E.g. the proper use of antidepressant, antiepileptic or analgesic drugs may not be considered as contraindication in some persons.
Denmark		The medical practitioner is in charge of deciding if and for how long the patient is not allowed to drive. If the medical practitioner assumes that the patient will not observe these rules, then he must address the medical officer of health in order to find a solution.
Estonia	No	
Finland	Yes	Yes after passed assessment: The guidelines of Ministry of Health and Social Affairs : (Päihderiippuvuuden arviointi ja ajokelpoisuus =) Assessment of Dependence and fitness to drive. Sosiaali- ja terveysministeriö: Päihderiippuvuuden arviointi ja ajokelpoisuus. Opas lääkäreille. Guidelines to physicians. STM, oppaita 1998:6, Helsinki 1998
France	Yes	No penal aspect, only the medical regulation of 21 12 2005 about "administrative" fitness to drive. No special mention about 1 st , recidivism or BAC levels)
Germany	Yes	Person has to undergo a medical-psychological Examination (MPU), the final decision is made by the driving license authority.
Greece	Yes	There are under the general law of testing driving ability after the treatment. Only the case of Alcohol defers regarding traffic

		regulations
Hungary	No	
Italy	Yes	
Luxemburg	Yes	After treatment and assessment by the medical commission of the Ministry of Transport
Netherlands	Yes	Certain BAC levels or driving under influence of drugs will result in a report by the police of the offender at the Dutch Driving Skills Authorities (CBR). CBR will send the offender to a psychiatrist. The offender is obliged to cooperate. When this psychiatrist diagnose abuse of a substance, the driving license will be taken away. When a person who lost his driving license due to abuse of alcohol or drugs has stopped his substance abuse for one year he can reapply. He will be examined again by a psychiatrist
Norway	-	
Slovakia	No	
Spain	Yes	Rehabilitation have to be prove through a mandatory reporting fulfilled by a psychologist or a psychiatrist. In any case, must have to pass one year from the start of the rehabilitation program. Neither recidivism nor analytical tests are mandatory in Spain, although in fact some analytical procedures used to be asked to the driver.
Switzerland	Yes	
Sweden	Yes	When having been without such use for a long enough time, verified by urine testing. Everyone who is convicted of gross drunk driving with a BAC over 0.1 % should prove that he/she does not have such a diagnosis. There are clear legal regulations on this in the same regulations mentioned above. (f.i. does one look for medical problems in offenders; and when (1st time, second time or recidivists; based on BAC levels?); who decides (judge, legal framework) See above

8.b Which assessment approach(es) is(are) used to assess the fitness to drive? (Multiple answers are possible)

- Medical approach
- Psychological approach
- Others, please specify: _____

Belgium		Medical approach Psychological approach practical driving test
Bulgaria		Psychological approach
Czech		Medical approach Psychological approach
Denmark		Medical approach
Estonia		Medical approach
Finland		Medical approach
France		Medical approach Psychological approach
Germany		Medical approach Psychological approach practical driving test
Greece		Medical approach
Hungary		Medical approach Psychological approach
Italy		Medical approach Psychological approach
Luxemburg		Medical approach
Netherlands		Medical approach
Norway		-
Slovakia		-
Spain		Medical approach Psychological approach
Switzerland		Others, please specify: Dependent on individual case, can be – but does not have to be - both

Sweden		-
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8.c In case several approaches are being used, is the final fitness to drive decision a medical decision?

Yes No

Belgium	Yes	
Bulgaria	-	
Czech	Yes	
Denmark	-	
Estonia	-	
Finland	Yes	
France	Yes	
Germany	No	Driving license authorities make the final decision.
Greece	Yes	Usually, if the medical test fails there is total rejection
Hungary	Yes	
Italy	Yes	
Luxemburg	-	
Netherlands	-	
Norway	-	
Slovakia	-	
Spain	Yes	
Switzerland	No	it is a judicial decision
Sweden	Yes	

8.d Does the fitness to drive assessment procedure differ by offender group category (such as for example: alcohol offenders, drug offenders, young drivers, addicts, recidivists)?

Yes No

If yes, please specify the different offender group categories: _____

Belgium	No	
Bulgaria	No	The psycho tests are to be implemented only in the cases, specified in Ordinance Nr. 36. These cases comprise alcohol and drug offenders, but they are also used in case of professional drivers, where no offence exists.
Czech	Yes	It depends on the circumstances and individual decision of general practitioners cooperating with other specialists.
Denmark	Yes	Drug addicts in substitution treatment, see VEJ 42.
Estonia	No	
Finland	No	
France	No	
Germany	No	(the MPU is obligatory for all offender groups, but it differs in the methods according to the circumstances – f.i. drug tests for drug offenders, but no drug test for people with multiple traffic offences)
Greece	Yes	An individual that belongs to the patients' category is obliged to go through higher medical committee in state hospitals under the inspection of 5 clinic directors who give the final medical result
Hungary	No	All type of addiction (alcohol, illicit drugs) are exclusion criteria
Italy	No	
Luxemburg	No	
Netherlands	Yes	Young offenders enter the procedure at lower BAC levels Recidivist enter the procedure at lower BAC levels

Norway	No	
Slovakia	-	
Spain	No	
Switzerland	No	see answer 8b
Sweden	Yes	The time to qualify for a new license after committing a gross drunk driving offence is used to diagnose if there is a condition of abuse or dependency, regardless if the crime is related to narcotic drugs or alcohol. No difference between offenders of different age.

9. In case a medical practitioner is responsible for the final decision regarding the fitness to drive, are there legal consequences in case his/her decision led to granting or renewing the driving license and an accident happened?

Yes No
 If yes, please specify:

Belgium	Yes	the Medical Practitioner who signs the document is responsible for his decision. For example an insurance company could contradict this.
Bulgaria	-	
Czech	Yes	It is the matter of criminal law concerning the Forgery and distorted documentation issue of medical assessment, medical finding and medical report, Penal code 140/1961 article 177b.
Denmark	No	
Estonia	No	
Finland	No	
France	No	
Germany	No	
Greece	Yes	It will be used from the lawyers against the medical doctor at court In a loose way and only if any related authority (or officer) have any suspicion on fitness
Hungary	Yes	
Italy	No	As mentioned above, they frequently pay insurances for that, by the fees are low, because the lack of responsibility is guaranteed by the existing legal frame.
Luxemburg	No	
Netherlands	No	
Norway	No	
Slovakia	No	
Spain	No	
Switzerland	-	As mentioned above, the medical practitioner is not responsible. Legal consequences are decided upon by the judicial decision.
Sweden	-	The practitioner gives his judgement but the decision is made by the authorities.N

9.a Do noteworthy numbers of court cases exist?

Yes No Don't know

If yes, please specify the number of cases (estimation of cases/year): _____

Belgium	Don't know	
Bulgaria	Don't know	
Czech	Don't know	
Denmark	Don't know	
Estonia	Don't know	
Finland	Don't know	
France	No	
Germany	No	
Greece	Don't know	
Hungary	No	A few cases per year
Italy	Don't know	
Luxemburg	Don't know	
Netherlands	Don't know	
Norway	-	
Slovakia	Don't know	
Spain	No	
Switzerland	(Yes)	Not possible. Many Remark: must be a misunderstanding
Sweden	No	

10. Have there ever been any efforts in your country to evaluate the impact of the current above mentioned regulations/guidelines on traffic safety?

Yes No Don't know

If yes, please give a short description of the evaluation and the literature reference in case it has been published:

Belgium	No	
Bulgaria	Don't know	In case of further questions, please contact the Ministry of Transport (http://www.mt.government.bg/index.php).
Czech	Don't know	
Denmark	Don't know	
Estonia	Don't know	
Finland	Yes	Päivi Rantanen, Mirja Mäkelä, Riitta Alaja, Kari Luotonen, Kaija Seppä : Intoxicants and the driving licence. Helsinki 2001, 69 p. (Reports of the Ministry of Social Affairs and Health, ISSN 1236-2115;2001:8, ISBN 952-==-1016-5
France	No	
Germany	No	
Greece	No	Only some proposals and discussions in parliament but with no result for the moment.
Hungary	No	Some publication relate to the necessity of a guideline or a more detailed regulation
Italy	-	The National institute of Health, depending from the Health Ministry, explicitly regrets the lack of these efforts. The Italian Senate inserted in the elaboration of the new Road Code a provision of all these guidelines mentioned in the above questions as due to be issued by the Government within six months from the approval of the new Law (not yet approved, but close to be). The CNEL (Italian Social and Economic Committee) strongly supported this new regulation, through an official advice to the Parliament. This should change a lot the situation.
Luxemburg	No	
Netherlands	Yes	A report by DHV (http://parlis.nl/blg4269.pdf) on the procedure mentioned above (2004: Evaluatie

		Vorderingsprocedure). This report states that the procedure of mandatory examination by a psychiatrist to determine abuse of substance means a reduction of 23 fatalities per year.
Norway	-	
Slovakia	Don't know	
Spain	No	
Switzerland	-	Few Swiss evaluation studies <u>Dubey Y, Gujer HR.</u> [Alcohol intoxication at the wheel in the Waadt canton (Switzerland).A comparative study of penal and administrative measures 1970 and 1989 in the canton capital city (Lausanne) and a rural area] Blutalkohol. 1993 Sep;30(5):266-89. German.
Sweden	Yes	The research process on these procedures are not very many but some are mentioned below, includingh the special project on alcohol interlock system.

3. Recommendations

WP 7 Partners have discussed the opportunities to improve guidelines and procedures for assessing fitness to drive based on the progress made within DRUID Workpackages 4 and 7. As explained in the introductory note of this Deliverable reflections are made on the existing guidelines and regulations. In these reflections reference has been made to the DRUID categorization system for medicines affecting driving performance. Although this categorization system will be described in more detail in Deliverable 4.2.1. (Establishment of criteria for a European categorisation system for medicinal drugs and driving) a short description of the different categories will be given to serve as background information while reading the recommendations based on the reflections in this chapter.

A European categorization system

The experts from Drug Regulatory Agencies in Europe and within the DRUID-consortium agreed on 4 categories to inform the patient and the health care providers on the medicine's impairing effects on driving. These are derived from the revised version of the SmPC (Summary of Product Characteristics), as proposed to EMEA in March 2008 during the consultation phase for the guideline on the SmPC.

Based on these 4 categories information for physicians and pharmacists can be derived, where the comparison with the effects of alcohol is suggested for communicating a level of impairment. In order to be more patient friendly the experts suggest more informative warning levels (see Table 2).

Warning levels to inform patients can be developed based on the 4 categories. It is emphasized that the warning can be based on warning symbols or pictograms, but that a description or explanation in writing or printing should always be an integral part of the warning symbol.

The following scheme (Table 2) can be considered as the proposal for a European categorization system, based on the conclusions by the experts from Drug Regulatory Agencies and DRUID partners:

Table 2: Proposed DRUID Categorization system.

Information for physicians and pharmacists		Warning for patients (with warning symbols and standard descriptions per country)
Description of categories with levels of impairment	Information on how to advise their patients	
Category 0 Presumed to be safe or unlikely to produce an effect on fitness to drive.	Confirm that the medicine will be safe for driving, provided that combinations with alcohol and other psychotropic medicines are excluded.	[no warning needed]
Category 1 Likely to produce minor adverse effects on fitness to drive.	Inform the patient that impairing side effects may occur especially during the first days and that have a negative influence on his/her driving ability. Give the patient the advice not to drive if these side effects occur.	Warning level 1 Do not drive without having read the relevant section on driving impairment in the package insert.
Category 2 Likely to produce moderate adverse effect on fitness to drive.	Inform the patient about the possible impairing side effects and the negative influence on his/her driving ability. Advise the patient not to drive during the first few days of the treatment. If possible prescribe a safer medicine, if acceptable by the patient.	Warning level 2 Do not drive without advice of a health care professional. Read the relevant sections on driving impairment in the package insert before consulting the physician or pharmacist
Category 3 Likely to produce severe effects on fitness to drive or presumed to be potentially dangerous.	Inform the patient about the possible impairing side effects and the negative influence on his/her driving ability. Urgently advise the patient not to drive. Consider prescribing a safer medicine, if acceptable by the patient.	Warning level 3 Do not drive. Seek medical advice after a period of treatment about the conditions to restart driving again.

* The assigned categories relate to the acute or first time use of the medicine (at the start of treatment)

3.1. Revising Art.15 in Council Directive 91/439/EEC

COUNCIL DIRECTIVE of 29 July 1991 on driving licences (91/439/EEC)

DRUGS AND MEDICINAL PRODUCTS

15. Abuse:

Driving licences shall not be issued to or renewed for applicants or drivers who are dependent on psychotropic substances or who are not dependent on such substances but regularly abuse them, whatever category of licence is requested.

Regular use:

Group 1:

15.1. Driving licences 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. This shall apply to all other medicinal products or combinations of medicinal products which affect the ability to drive.

Group 2:

15.2. The competent medical authority shall give due consideration to the additional risks and dangers involved in the driving of vehicles covered by the definitions of this group.

The WP 7 Partners have discussed and reflected on the text of Art 15. of Council Directive 91-439-EEC and concluded that recommendations for common European guidelines could be drafted based on their reflections, partially integrating the results of the questionnaire survey as described in Section 2 of this Deliverable and the current regulations in Europe. It takes special efforts to derive at consensus at a European level; therefore it is recommended that working groups and expert rounds should discuss the proposed recommendations as presented below with physicians, pharmacists, driving licensing authorities and policy makers.

Recommendations based on reflections

Recommendation 1

It is strongly advised to separate medicines from substances other than alcohol in Article 15. It should be made clear that for “substance abuse” and “substance dependence” different definitions exist, according to the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-R), whereas the definition of “abuse” is criticized in the current review of DSM-V. A clinical description of the dependence syndrome in the International Classification of Disease and Health problems

(ICD-10) focuses on the central characteristic of the desire to take psychoactive drugs (which may or may not have been medically prescribed).

Recommendation 2

It is pointed out that a similar concern exists regarding definitions related to the terms 'medicines' and 'drugs' in professional as well as in layman's context. A suggestion could be to use the definitions for 'medicines' provided by the EMEA¹. For 'drugs' the definitions provided by the World Health Organisation in their Lexicon of alcohol and drug terms could be used.² The term 'drug' often refers specifically to psychoactive drugs, and often, even more specifically, to illicit drugs, of which there is non-medical use in addition to any medical use. Professional formulations (e.g. "alcohol and other drugs") often seek to make the point that caffeine, tobacco, alcohol, and other substances in common non-medical use are also drugs in the sense of being taken at least in part for their psychoactive effects.

Recommendation 3

In formulating the criteria for fitness to drive it should always be very clear that a fitness to drive decision is an overall decision, in the sense that the applicant should meet 'all' criteria. The fitness to drive related to the use of 'drugs and medicinal products' is only one aspect of this decision. The overall decision takes into account the underlying cause or reason for taking medicines, as well as all co-morbidity factors. For the latter evaluation reference should be given to the respective chapters in Annex III of the Driving Licence Directive.

¹ 2001/83/EC Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (Consolidated version : 30/12/2008).

² Lexicon of alcohol and drug terms published by the World Health Organization.

http://www.who.int/substance_abuse/terminology/who_lexicon/en/index.html

psychoactive drug or substance A substance that, when ingested, affects mental processes, e.g. cognition or affect. This term and its equivalent, psychotropic drug, are the most neutral and descriptive terms for the whole class of substances, licit and illicit, of interest to drug policy.

"Psychoactive" does not necessarily imply dependence-producing, and in common parlance, the term is often left unstated, as in "drug use" or "substance abuse".

A cultural-political debate over whether general descriptive terms would give a favourable or unfavourable cast to the experience of mind-changing was conducted in many European and English-speaking countries in the 1960s and 1970s with regard to LSD and similar drugs. The terms "psychotomimetic" and "hallucinogen" (the latter became the accepted name for this class of drugs) conveyed an unfavourable connotation, while "psychedelic" and "psychoactive" gave a more favourable cast. "psychedelic", in particular, was also used with the same broad scope as "psychoactive" (The *Journal of psychedelic drugs* eventually changed to "psychoactive" in its title in 1981.)

Recommendation 4

It is strongly advised to avoid the term “regular use”, because this is confusing since “chronic treatment” in medical descriptions can have different definitions, depending also on the group of medicines concerned. Most medicines categorized as “severely impairing” (category III in the proposed DRUID categorization system) used by drivers will have different effects upon driving after single use, after increasing the dose and after switching to another medicine or combining the medicine with another one, at the start of treatment (first few days), during the first 1-2 weeks and after chronic use (several months). These circumstances need to be considered in deciding on the issuing or renewal of driving licences and can be best considered in separate sections dealing with medicines presented as a therapeutic class (e.g. hypnotics, antidepressants). The use of a specific category III medicine can be considered compatible with driving if taken chronically, therefore the term “regular use” will not be distinctive enough. More important in this case is a statement in the Driving Licence Directive that circumstances can allow the physician to advise the patient to take into account specific precautions and comply to desired treatment behaviour in combining treatment and driving. This approach needs to be documented adequately by the physician (see also 3.1) and furthermore the patient needs to be aware that he or she will remain responsible for the decision whether or not to drive.

Recommendation 5

WP 7 Partners strongly advise to avoid the term “regular use” in case of illicit drug use, because this is confusing and not based on the current terminology used by the EMCDDA³. Drug consumption patterns (quantity used and type of use) should be taken into account, e.g. frequent use of cannabis (which may be defined as from a few days in the last 30, up to 40 times in the last 30 days) and the quantity of use on one side and the association of higher than average rates of both licit and illicit drug use (polydrug use) on the other⁴.

Recommendation 6

If ‘combinations of medicines with central nervous system activity’ are used as well as combinations of psychotropic medicines with other medication that can alter the metabolism of the psychotropic medicine (with a possible consequence of increased blood levels of the latter) this will always call for an individual judgement by the prescribing physician. This is especially of interest for drivers with co-morbidities and in case of polypharmacy.

It should be discussed whether it will be realistic to define criteria for deciding on a patient’s fitness to drive in the context of the Driving Licence Directive while using these combinations. If there are criteria defined the approach needs to be documented adequately by the physician (see also 3.1) and furthermore the

³ European Monitoring Centre for Drugs and Drug Addiction, Annual Report 2008: the state of the drugs problem in Europe.

⁴ European Model Questionnaire, explained in the EMCDDA Handbook

<http://www.emcdda.europa.eu/stats08/gps/methods>

patient needs to be aware that he or she will remain responsible for the decision whether or not to drive.

3.2. Application of the DRUID categorization system

Recommendation 7

It is recommended to apply the DRUID categorization system for medicines affecting driving performance in developing national requirements for fitness to drive. Based on a questionnaire survey among driving licensing authorities there is one country (The Netherlands) where a categorization system of medicines, very similar to the DRUID categorization, has been used for describing the minimal requirements for fitness to drive in issuing and renewal of driving licences. This example needs further consideration by other EU Member States.

3.3. Documentation of consultation

WP 7 Partners have discussed that in situations where physicians will advise a patient to start driving again after a period in which the advice was given not to drive while using the medicine, specific procedures are recommended to structure the consultation and to manage the risk of litigation in case an accident could occur.

Recommendation 8

It is recommended that the following actions are taken during the consultation:

1. Advise not to combine (psychotropic) medication without the advice of a physician or pharmacist and to avoid the combination with alcohol.
2. Check whether the patient is willing and able to follow the treatment plan and explain the patient's liability in case the patient is non-compliant to the treatment plan.
3. Advise the patient to be aware of possible side-effects and to refrain from driving in case these side-effects occur.
4. Advise the patient to report on these side-effects during a follow up visit.

And furthermore documentation of the following items in the patient's medical record:

1. Tests performed and / or information gathered in assessing fitness to drive.
2. Assessment of patient's decision-making competence based on advices given.
3. Patient's understanding of impairing properties of the medication.
4. Specific actions to achieve fitness to drive (changes in medication or instructions for use).
5. Follow up visit for evaluation of interventions (advices given, self-assessment of patient).