



# **Summary of Main DRUID Results**

Driving Under the Influence of Drugs, Alcohol, and Medicines

January 24<sup>th</sup> 2012 7:30 PM – 9:30 PM

Marriott Washington DC, USA

TRB 91<sup>st</sup> Annual Meeting

Sponsored by Alcohol, Other Drugs, and Transportation (ANB50)
TRB Event Number: 647

# Index

List of abbreviations and definitions		
Introdu	action and foreword of the Coordinator	4
Overvi	ew boxes	7
1.	ALCOHOL	7
2.	ILLICIT DRUGS	8
3.	PSYCHOACTIVE MEDICINES	11
4.	ENFORCEMENT	13
5.	CLASSIFICATION	13
6.	REHABILITATION	15
7.	WITHDRAWAL	16
8.	GUIDELINES AND RISK COMMUNICATION	17
DRUID	) Deliverables	18
DRUID	o consortium	21
DRUID implementation structure		23

# List of abbreviations and definitions

AT Austria

ATC Anatomical Therapeutic Chemical classification system

BAC Blood alcohol concentration

BASt Bundesanstalt für Straßenwesen (Federal Highway Research

Institute), DE

BE Belgium BG Bulgaria

BIVV Belgisch Instituut voor de Verkeersveiligheid, vzw (Belgian Road

Safety Institute), BE

BrAC Breath alcohol concentration

CA Canada

CBA Cost-benefit-analysis

CH Switzerland

CHMP Committee for Medicinal Products for Human Use

CMD (h): Coordination Group for Mutual Recognition and Decentralised

Procedures - Human

CSI Clinical Signs of Impairment

CY Cyprus

CZ Czech Republic

DE Germany; equivalent to GE

DG MOVE Directorate-General for Mobility and Transport of the EC DG SANCO Directorate General for Health and Consumer Affairs of the EC

DI Driver Improvement

DK Denmark

DR Driver Rehabilitation

DRET Driver Rehabilitation Evaluation Tool

DRUID Driving Under the Influence of Drugs, alcohol and medicines

DUI Driving under influence of alcohol
DUID Driving under influence of (illicit) drugs
DWI Driving while impaired/intoxicated
e.g. exempli gratia (Latin): for example

EC European Commission

EE Estonia EL Greece

EMA European Medicines Agency

ES Spain

et al. et alii (Latin): and others

ETSC European Transport Safety Council

EU European Union

EUR Euro
FI Finland
FR France
HU Hungary

IAPO International Alliance of Patients' Organisations

IBSR Institut Belge pour la Sécurité Routière, asbl (Belgian Road

Safety Institute), BE

ICADTS International Council on Alcohol, Drugs & Traffic Safety

IE Ireland

INRETS Institut National de Recherche sur les Transports et leur Sécurité

(National Institute for Transport and Safety Research), FR

IT Italy

KfV Kuratorium für Verkehrssicherheit (Austrian Road Safety Board), AT

LT Lithuania
LU Luxembourg

LV Latvia MT Malta

NA Not applicable
NL Netherlands
NO Norway
OR Odds ratio
p. Page

PhVWP PharmacoVigilance Working Party

PIL Patient Information Leaflet

PL Poland PT Portugal

PURS Police user requirements and specifications

RH Rehabilitation

RUGPha University of Groningen, Pharmacy, NL

SE Sweden
SI Slovenia
SK Slovakia

SmPC Summary of Product Characteristics

TEN\_TEA Trans-European Transport Network Executive Agency of the EC

THC Delta-9-tetrahydrocannabinol

THCCOOH 11-nor-9-carboxy- 9-tetrahydrocannabinol

UK United Kingdom

USA or US United States of America

vs versus

WP Work Package

# Introduction and foreword of the Coordinator

In 2001 there were 50 000 fatalities on European roads, prompting the European Commission to undertake a set of measures with the overall target of reducing the number of fatalities by 50% until 2011. The Integrated Project DRUID (Driving under the Influence of Drugs, Alcohol and Medicines) was launched in October 2006 within the 6<sup>th</sup> Research Framework Programme. DRUID aimed at getting new insights into the impact of psychoactive substances on road safety and producing recommendations for road safety policy makers. The project filled the existing knowledge gaps and provided a solid base to generate harmonised, EU-wide regulations with regard to combating driving under the influence of alcohol, drugs and medicine.

DRUID is the largest European research project in the domain of road safety in terms of geographic coverage (18 European countries; see Figure 1), budget (23.5 Mio. €) and number of partners (37 partners, listed on page 21). It brought together the best European expertise in the area of road safety. The Final Conference of DRUID took place on September 27<sup>th</sup> and 28<sup>th</sup> 2011 in Cologne, where all partners met to present project results to international experts and the representatives of the European Commission.

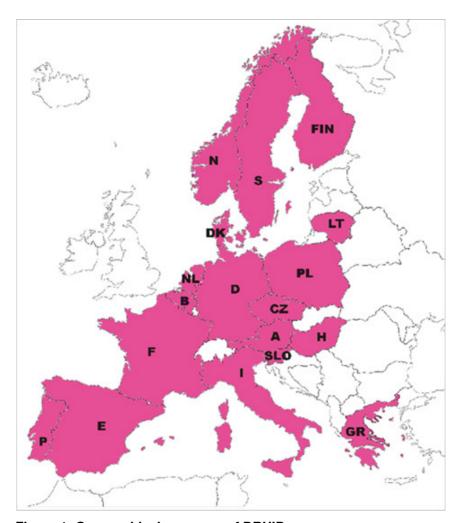


Figure 1: Geographical coverage of DRUID.

In the course of the project researchers had to cope with several challenges some of which could not have been foreseen before the project was launched. The hardest problems to address were national legal and ethical research constraints and the problem of comparing substance concentration values in different body fluids.

National legal and ethical constraints made the experimental and epidemiological studies very complex. It was extremely difficult to assure high scientific standards of the studies under conditions imposed by these constraints. A conversion of substance concentration values between different body fluids collected in the epidemiological studies is a problem that was not adequately assessed and addressed before DRUID. Normally, whole blood is analyzed to determine the concentration of a given substance. While blood samples could be collected from drivers injured or killed in an accident, this was not possible in all roadside surveys in which only saliva samples could be collected instead. Therefore a solution had to be found to enable a comparison of the data based on concentration values in different body fluids.

This brochure offers an overview of the project results. For more detailed information the final report and all deliverables are available on the DRUID website (<a href="www.druid-project.eu">www.druid-project.eu</a>).

DRUID activities were implemented in seven scientific Work packages. A description of the problem situation of driving under the influence of psychoactive substance (DUI/DUID) was generated in WP1 and WP2 based on experimental and epidemiological studies, whereas the remaining five Work packages focused on countermeasures to combat DUI/DUID.

The major work contents of the scientific Work packages were:

- Data on prevalence of psychoactive substances in the general driving population was collected in roadside surveys conducted in 13 European countries according to a uniform study design. For this purpose samples of body fluids of approximately 50 000 randomly selected drivers have been analyzed (WP2).
- Risk estimates for driving under influence of psychoactive substances have been derived from the case-control study in which data of the roadside surveys was linked to the data of approximately 4 500 drivers seriously injured or killed in an accident (WP2).
- Characteristics of drivers tending to drive under the influence of psychoactive substances were identified (WP2).
- A description of the current state of research on the impact of alcohol, illicit drugs and medicines on driving was given based on meta-analyses and reviews (WP1).
- 13 driving tests were conducted according to a uniform study design to close knowledge gaps on the impact of major illicit drugs and medicines on driving performance (WP1).
- Oral fluid screening devices and checklists for identifying clinical signs of impairment have been evaluated (WP3).
- A cost-benefit analysis of increased anti-drug enforcement through traffic police was done (WP3).
- A four level classification and labelling system for medicines regarding their influence on driving performance was created (WP4).
- The most comprehensive database on European rehabilitation schemes and measures as well as on quality assurance measures for rehabilitation programs was established (WP5).
- A compilation of practices of driving license withdrawal in Europe and recommendations concerning best practice for withdrawal/ licensing strategies was made (WP6).

- Guidelines for health care professionals on prescribing and dispensing medicines were developed taking their impact on driving performance into account (WP7).
- Recommendations on how to disseminate the DRUID results to different target groups, i.a. general public, young drivers, patients, health care professionals, policy makers were produced (WP7).
- Recommendations for policy makers on a European level have been derived from the results of all Work packages.

I would like to thank all DRUID partners and especially the Work package leaders for their tremendous contribution to project success. I would like to express my gratitude to peer reviewers who provided their expert knowledge to enhance the quality of our deliverables. Without the close collaboration with the European Commission and especially with the Project officers Joel Valmain and Maria-Cristina Marolda it would not be possible to complete this project with such success.

We are grateful to TRB for offering the opportunity to present DRUID to international road safety research community. On behalf of the Federal Highway Research Institute (BASt) I wish TRB participants a fruitful and pleasant work.

Dr. Horst Schulze DRUID Coordinator

#### **Overview boxes**

The main DRUID results on the following topics have been summarized in D7.3.2. Within this deliverable each topic description has been merged into overview boxes which are presented below.

#### 1. Alcohol

#### Box 1: Summary of main DRUID results – ALCOHOL (D7.3.2, p. 60-61)

#### Prevalence of alcohol in relation to road safety:

- Alcohol (≥0.1g/L) is the most frequently detected psychoactive substance in the driving population (estimated EU mean 3.48%) (D2.2.3) as well as in the seriously injured (range 17.7-42.5%) and in killed drivers (range 19.0-44.9%) in Europe (D2.2.5; D2.2.4; D2.3.4).
- General driving population (D2.2.3):
  - Alcohol alone (≥0.1g/L): most frequently detected substance in most countries; estimated EU mean prevalence 3.48% (range 0.15-8.59%); prevalence ranking from all investigated substances #1; main EU region: Southern Europe;
  - Alcohol alone (≥0.5g/L): estimated EU mean prevalence 1.49% (range 0.07-5.23%): prevalence ranking from all investigated substances #2;
  - Alcohol alone (≥1.2/L): estimated EU mean prevalence about 0.40% (range 0.01-1.47%); prevalence ranking from all investigated substances #6;
  - o Total alcohol (single + combined): estimated EU mean prevalence about 3.87% (range 0.18-9.6%).
- Seriously injured and killed drivers (D2.2.5; D2.2.4; D2.3.4):
  - Hospital study: alcohol (≥0.1g/L) was the most common toxicological finding, both in the seriously injured (range 17.7-42.5%) and in killed drivers (range 19.0-44.9%); Respective findings for alcohol (≥0.5 g/L) were 16.1-38.2% for seriously injured drivers and 16.3–35.1% for killed drivers (D2.2.5);
  - Fatal accident database FR (D2.2.4): prevalence rate of alcohol 25% (followed by THC, opiates, amphetamines and cocaine) (D2.2.4);
  - Responsibility study in DE, LT, HU, SK (D2.3.4): about 37% of all tested drivers were under the influence of alcohol.

#### Characteristics of drivers tested positive for alcohol:

- Alcohol was in the general driving population mainly detected among older male drivers, with lower BAC levels (D2.2.3).
- Within the accident involved drivers alcohol was mainly detected among younger male drivers with a high BAC level (D2.2.5).
- General driving population (D2.2.3):
  - Most prevalent in the two oldest age groups (35-49 and 50+);
  - More prevalent in male than in female drivers;
  - Main prevalent periods: weekday nights and weekends;
  - In general the largest prevalence for alcohol is present at low BAC level (exception: LT were 40% of alcohol drivers had BAC >1.2g/L) (D2.2.3).
- Seriously injured and killed drivers (D2.2.5, D2.2.4):
  - Most prevalent in young drivers (25-35 years) (D2.2.5):
  - More prevalent in male than in female drivers (about 70/30 in seriously injured and 83/17 in the killed drivers) (D2.2.5);
  - Majority of seriously injured or killed drivers tested positive for alcohol had a high BAC level; 90.5% of injured drivers (87% of killed drivers) had BAC ≥0.5g/L (D2.2.5); majority of positive tested drivers for alcohol were severely intoxicated (BAC ≥1.2 g/L) (D2.2.4).

- Motives behind impaired driving (D2.2.1):
  - o Drivers do not think that alcohol impairs their performance;
  - Orivers whose drinking and driving was related to problems with alcohol argue that losing the licence or even to be imprisoned would not have helped them to stop reoffending; instead, they argue that the treatment programme had helped them by providing a greater insight into their own problems.

#### Accident risk for driving with alcohol:

- Alcohol highly increases accident risk (e.g. D2.3.2; D2.3.3; D2.3.4; D2.3.5).
- Based on case- control studies, the relative risk of serious injury or fatality for alcohol (≥0.5g/L) is found to be significantly increased compared to that of drivers below the DRUID cut-off for any substance (D2.3.5).
- An increased risk was associated with high BAC level, young age and speed (D2.3.3).
- The risk increases drastically with combined use (e.g. cannabis) (D2.3.2).
- The results of the DRUID accident risk studies reveal:
  - Responsibility studies (D2.3.2, D2.3.3, D2.3.4): the risk of being responsible for a fatal crash is 5-8 times higher for a driver driving under the influence of alcohol ((≥0.1g/L) than for a sober driver; severely intoxicated drivers (alcohol ≥1.2 g/L) have a 15-21 times higher risk of being responsible for a fatal crash compared to sober drivers.
  - Case control study (D2.3.5): relative risk of serious injury or fatality for a driver when positive for alcohol ( $\geq$ 0.1g/L) is estimated to be about 5-10 times (for: 0.1-0.5g/L  $\rightarrow$  1-3 times; 0.5-0.8g/L  $\rightarrow$  2-10; 0.8-1.2g/L  $\rightarrow$  5-30 times; and  $\geq$ 1.2 g/L  $\rightarrow$  20-200 times) as high as that of drivers below the DRUID cut-off for any substance.

Results from experimental studies on the effect of alcohol on driving performance:

- Alcohol has a negative impact on driving performance and on skills related to driving (e.g. D1.1.2a).
- Driving tests are important to estimate impairment effects, as unspecific measures of psychomotor performance do not fully represent the driving performance decrements caused by alcohol (e.g. D1.1.2a).

# 2. Illicit drugs

# Box 2: Summary of main DRUID results – ILLICIT DRUGS (D7.3.2, p. 70-72)

Prevalence of illicit drugs in relation to road safety:

- All DRUID investigations (e.g. D2.2.3, D2.2.5, D2.3.4) show that the prevalence of illicit drugs in the driver population (estimated EU mean 1.90%) is lower than the alcohol prevalence (estimated EU mean 3.48%) (D2.2.3).
- Within the accident involved drivers, the majority of drugs appeared to be used in combination with other psychoactive substances (mainly alcohol) (D2.2.5).
- THC is generally the most frequently detected illicit drug, followed by cocaine, but the prevalence of the different illicit substances show high national variability (e.g. D2.2.3, D2.2.5, D2.3.4).
- General driving population (D2.2.3):
  - Illicit drugs: estimated EU mean for one or more illicit substances 1.90% (range 0.22-8.20%); main EU region: Southern Europe;
  - THC alone: estimated EU mean prevalence 1.32% (range 0-5.99%); prevalence ranking from all investigated substances #3; main EU region: Southern Europe; on average 20-30% of THC use was in combination with other psychoactive substances;
  - Cocaine alone: estimated EU mean prevalence 0.42%, (range 0-1.49%); prevalence ranking from all investigated substances #5; main EU region: Southern Europe; on average around 50% of cocaine use was in combination with other psychoactive substances;

- Amphetamine alone: estimated EU mean prevalence 0.08%; (range 0-0.38%); prevalence ranking from all investigated substances #11; main EU region: no specific region; on average around 50% of amphetamine use was in combination with other psychoactive substances;
- Illicit opiates alone: estimated EU mean prevalence 0.07%; (range 0-0.30%); prevalence ranking from all investigated substances #12; main EU region: Southern Europe; illicit opiates were relatively frequently used in combination with other psychoactive substances;
- O Alcohol (≥0.1g/L) drug combinations: estimated EU mean prevalence 0.37% (range 0.0-1.14%); prevalence ranking from all investigated substances #8; main EU region: Southern Europe; relative proportion varies between 0-23%; Countries with higher prevalence for single alcohol and single drug use have, as expected, higher prevalence for combined use of alcohol and drugs;
- Drug-drug combinations: estimated EU mean prevalence 0.39% (range 0-1.22%); prevalence ranking from all investigated substances #7; main EU region: Northern Europe; most commonly used drugs in multi-drug combinations are THC, cocaine, and benzodiazepines; proportion of multi-drug use is on average around 10% of all drug use (highest in IT where 22% of the drug using had been using two or more different drugs.
- Seriously injured and killed drivers (D2.2.5; D2.2.4; D2.3.4):
  - o Hospital study: no clear picture of the distribution of illicit drugs among injured and killed drivers could be identified, as the prevalence of different substances showed great national variability. Seriously injured drivers: THC (range 0.5-7.6%) second most common toxicological finding after alcohol. Amphetamine use more common in northern Europe; cocaine use more prevalent in southern Europe. Killed drivers: THC was number four (range 0- 6.1%), after alcohol, benzodiazepines and amphetamines. Combined user (alcohol-drug and drug-drugs): The majority of drugs appeared to be used in combination with other psychoactive substances (mainly alcohol). The group of alcohol-drug combined users were within the seriously injured drivers and killed drivers second most represented group in almost all countries. The combined use of "drug-drug" represent either third or fourth biggest group for percentage of positive subjects among seriously injured drivers (D2.2.5).
  - o Responsibility study in DE, LT, HU, SK (D2.3.4): about 4.3% of all tested drivers were under the influence of illicit drugs (mainly cannabis).

#### Characteristics of drivers tested positive for illicit drugs:

- Illicit drugs were in general mainly detected among young male drivers, during all times of the day but mainly at the weekend (D2.2.3).
- Combined use of alcohol and drugs (illicit drugs and/or psychoactive medicine) is in general often prevalent among young (<35 years) male drivers during night time hours (D2.2.3).
- Multiple drugs (illicit drugs and/or psychoactive medicines) use is in general most common in males (D2.2.3).
- Age groups and time periods vary considerably by country (D2.2.3).
- General driving population (D2.2.3):
  - Cannabis in drivers in traffic (D2.2.3):
    - Most prevalent among young drivers (18-34 years);
    - 2-3 times more prevalent in male than in female drivers;
    - Main time period differs per country.
  - Cocaine in drivers in traffic (D2.2.3):
    - Almost all cocaine users younger then 50 years; within logistic regression (BE, NO, HU PT) highest prevalence would be found among the age group 25-34;
    - 2 times more prevalent in male than female drivers;
    - Main time period differs per country.
  - Amphetamines in drivers in traffic (D2.2.3):
    - Most prevalent among young drivers (18-35 years);
    - The gender effect differs by country;
    - Main time period differs per country.

- Illicit opiates (D2.2.3):
  - Most prevalent among middle aged drivers (35-49 years);
  - More prevalent in male than in female drivers;
  - Main time period differs per country.
- Alcohol and drugs combination (D2.2.3):
  - Most prevalent among young drivers (18-34);
  - More prevalent in male than in female drivers;
  - Most commonly detected in night-time hours.
- o Drug-drug combination (D2.2.3):
  - Mainly detected in middle aged drivers (<50);</li>
  - More prevalent in male than in female drivers;
  - Main time period differs per country.
- Seriously injured and killed drivers (D2.2.5):
  - Most prevalent in young and middle aged drivers (<50 years),</li>
  - More prevalent in male than in female drivers;
  - The majority of drugs appeared to be used in combination with other psychoactive substances (mainly alcohol).
- Motives behind impaired driving (D2.2.1; D2.2.2):
  - Addicted drivers did not believe that they would be stopped by the police (D2.2.1)
  - They did not believe that alcohol or drugs would impair their driving and therefore they did not perceive any real risks of driving (D2.2.1).
  - o Findings indicate that especially moderate substance users can realistically judge their intoxication and are responsible-minded concerning drugs in traffic (D2.2.2).

### Accident risk for driving with illicit drugs:

- Based on case-control studies, the relative risk of serious injury or fatality for different illicit substances varies between the substances. For: THC about 1-3 times; benzoylecgonine, cocaine and illicit opiates about 2-10 times; amphetamines about 5-30 times) as high as that of drivers below the DRUID cut-off for any substance. Some of the risk estimates for illicit drugs vary to a high degree among the single countries; others are based on few positive cases and/or controls which result in very wide confidence intervals. Therefore the estimates are uncertain. (D2.3.5; see also D1.1.2b, D1.2.1, D2.3.2).
- The risk multiplies with combined use (e.g. alcohol) (e.g. D2.3.2, D2.3.5).
- DRUID accident risk studies:
  - Responsibility study FR (D2.3.2): drivers involved in fatal accidents and positive for cannabis (≥1 ng/ml), had a risk of about twice as high as that of drivers not positive for cannabis (adjusted OR 1.89 [95% CI 1.43-2.51]) (in comparison alcohol: 8 times as high (adjusted OR 8.39 [95% CI 6.95-10.11]). Combined use of alcohol and cannabis multiplies the risk of causing a fatal accident (8.39\*1.89=15.86).
  - Case control study (D2.3.5): relative risk of serious injury or fatality for a driver when positive for different illicit substances is estimated to be about 1-30 times (for: THC → 1-3 times; benzoylecgonine and cocaine → 2-10; amphetamines 5-30 times) as high as that of drivers below the DRUID cut-off for any substance.

#### Results from experimental studies on the effect of illicit drugs on driving performance

- Experimental studies have shown that the dose equivalent for BAC 0.5g/L-3.7ng/mL THC (range 3.1-4.5ng/mL) for oral administration and 3.8 ng/mL (range 3.3-4.5ng/mL) for smoked administration (D1.1.2b, see also D1.4.2 for more information on cut-offs equivalent to BAC 0.5g/L).
- Experimental studies evaluating the effect of stimulants on driving (MDMA and dexamphetamine) did not reveal impairing effects on driving performance. However, the stimulant effects of MDMA and dexamphetamine are not sufficient to overcome or compensate driving impairments produced by concomitant of alcohol use or sleep deprivation (D1.1.2b, D1.2.1).

# 3. Psychoactive medicines

#### Box 3: Summary of main DRUID results – PSYCHOACTIVE MEDICINES (D7.3.2, p. 79-81)

Prevalence of psychoactive medicines in relation to road safety:

- DRUID studies indicate that some selected psychoactive medicines (benzodiazepines, medicinal opiates and opioids and Z-drugs) are less prevalent in the driving population (estimated EU mean 1.4%) (D2.2.3) as well as is in seriously injured drivers (D2.2.5) compared to alcohol (estimated EU mean 3.48%) and illicit drugs (estimated EU mean 1.90%). Among the killed drivers the presence of benzodiazepines was the second most frequent toxicological finding after alcohol (D2.2.5). Psychoactive medicines, such as (frequently used) antidepressants, anti-epileptics and antipsychotics, were not included in the DRUID studies. Therefore an underestimation of prevalence should be considered.
- In most countries benzodiazepines were the most common psychoactive medicines in traffic but as for illicit drugs the prevalence of the different psychoactive medicines show high national variability (D2.2.3, D2.2.5).
- Epidemiological studies indicate a major increase in the consumption of antidepressants and drugs used in addictive disorders in the general population in Europe within the last years (D2.1.1).
- General driving population (D2.2.3):
  - Psychoactive medicines: estimated EU mean for one or more psychoactive medicine
     1.36% (range 0.17-2.99%); main EU region: no specific region;
  - Benzodiazepines alone: estimated EU mean 0.90% (range 0.14-2.73%); prevalence ranking from all investigated substances #4; main EU region: Southern Europe; not often used in combination with other psychoactive substances (proportion around 15% in most countries);
  - Medicinal opiates and opioids alone: estimated EU mean 0.35% (range 0.00-0.79%); prevalence ranking from all investigated substances #9; relatively often used in combination with other psychoactive substances; in CZ, ES and PL only single use was detected;
  - Z-drugs alone: estimated EU mean 0.09% (range 0-0.69%); prevalence ranking from all investigated substances #10; relatively often combined with other psychoactive substances.
- Seriously injured and killed drivers (D2.2.5; D2.2.4; D2.3.4):
  - Hospital study: no clear picture of the distribution of psychoactive medicines among injured and killed drivers could be identified, as the prevalence of different substances showed great national variability. Seriously injured drivers: benzodiazepines (range 0.0-10.2%) were third most frequent finding after alcohol and THC. Killed drivers: benzodiazepines (range 1.8-13.3%), were the second most found substance group after alcohol, followed by amphetamine (D2.2.5).
  - Responsibility study in DE, LT, HU, SK (D2.3.4): about 6% of all tested drivers were under the influence of psychoactive medicines (mainly benzodiazepines).

Characteristics of drivers tested positive for psychoactive medicines:

- Psychoactive medicines were in general mainly detected among older female drivers during daytime hours (D2.2.3).
- General driving population (D2.2.3):
  - Benzodiazepines in drivers in traffic (D2.2.3):
    - Most prevalent among middle aged and older drivers (35+);
    - More prevalent in female than in male drivers;
    - Most commonly detected in daytime hours.
  - Medicinal opiates in drivers in traffic (D2.2.3):
    - Most prevalent among middle aged and older drivers (35+);
    - More prevalent in female than in male drivers;
    - · Most commonly detected in daytime hours.

- Seriously injured and killed drivers (D2.2.5):
  - Most prevalent in middle aged and older drivers (35+);
  - More prevalent in male than in female drivers;
  - The majority of psychoactive substances appeared to be used in combination with other psychoactive substances (mainly alcohol and benzodiazepines).

#### Accident risk for driving with psychoactive medicines:

- Alcohol impaired driving is the main problem in traffic safety, but also psychoactive medicines can constitute a problem in traffic safety. Therefore, both health care providers and patients should be properly informed and aware of the potential risks associated with the use of psychoactive medicines (link WP4/7). Based on case-control studies, the relative risk of serious injury or fatality for benzodiazepines + Z-drugs and medicinal opioids) is estimated to be about 2-10 times (medicinal opioids in the upper part of the interval; benzodiazepines + Z-drugs in the lower part of the interval) as high as that of drivers below the DRUID cut-off for any substance (D2.3.5).
- DRUID accident risk studies:
  - NL study (D2.3.1): The risk of being involved in an accident is highest for users of modern antidepressants (1.76, CI: 1.38-2.24), followed by patients who use combinations of psychoactive medicines (1.55, CI: 1.20-2.02), and patients using at least one psychoactive medication (1.28, CI: 1.12-1.46).
  - Case control study (D2.3.5): The medium increase of the relative risk of serious injury or fatality for a driver when positive for benzodiazepines + Z-drugs and medicinal opioids) is estimated to be about 2-10 times (higher risk for medicinal opiods; lower risk for benzodiazepines + Z-drugs) (D2.3.5).

Results from experimental studies on the effect of psychoactive medicines on driving performance

- Psychoactive medicines can impair driving performance (e.g. D1.2.2, D1.1.2b, D1.1.2c).
   Besides the agent itself there are many factors influencing the degree of impairment (e.g. galenics, route of administration, dose, time period between administration and driving, concomitant use of other (medicinal) drugs, habituation).
- Zopiclone (7.5mg) and alprazolam (0.5mg) produced significant driving impairment in patients as well as in healthy controls during morning driving 10-11 hrs after drug intake (D1.2.2).
- The impairing potential of Codiliprane® varies with age (D1.2.2).
- Single doses (10 and 20mg) of Dronabinol (Marinol®) impaired road tracking performance of occasional cannabis users (representing acute effects of Dronabinol) during on-the-road driving tests in a dose related manner. Those impairments were bigger than the impairment caused by BAC of 0.5g/L (D1.2.2).
- After habituation transdermal application of opioid analgesics as well as oral administration of slow release formulations of opioid analgesics caused no impairment in patients suffering from chronic pain (D1.2.2).
- Even at low dosages methadone and buprenorphine caused impairment when given as a single dose to healthy subjects. No clear evidence exists if patients under maintenance treatment are able to drive safely. Many maintenance patients use other substances in addition, so it is recommended that a screening for other substances is done if a maintenance patient should be allowed to drive (D1.1.2c).

# 4. Enforcement

#### Box 4: Summary of main DRUID results - ENFORCEMENT (D7.3.2, p. 86-87)

- DRUID provides guidelines for everyday drug-driving police enforcement and installs scientific demands for on-site screening for impairing psychoactive substances other than alcohol in drivers (e.g. legal frame, basic standards of procedure and devices) (D3.1.1, D3.2.1, D3.2.2).
- First enforcement priority should always lie on alcohol, other drugs are second priority (D3.3.1).
- Characteristics of the problem situation on national level determine the focus (and devices) of drug enforcement (D3.3.1).
- Increase of drug enforcement is potentially cost-beneficial, especially for countries that currently have a low enforcement level. It will NOT be beneficial if this increase is financed (time and money) at the cost of drink-driving enforcement (D3.3.1).
- The effectiveness of drug-driving enforcement can be enhanced by e.g. (D3.3.1):
  - Using on-site screening devices which fulfil practical as well as scientific requirements (two major benefits of saliva screening for drugs are that saliva collection is much less invasive than urine and blood collection and that it better detects recent drug use than in urine, sweat or hair; Cost-Benefit Analysis (CBA): emphasis on high specificity).
  - o Ideally large-scale random drug testing (largest general deterrence effects) is done, but this is not feasible in practice since the devices are too expensive and take too much time for sample collection and analysis. The effectiveness can also be enhanced by: pre-selection of time, place and target group (e.g. alcohol impaired drivers), based on specific characteristics of the problems (national and regional level).
  - Clinical Signs Inventory (CSI) checklist as working method to preselect suspected drivers for on-site drug screening, did not give very encouraging results; more experience and better training of police may improve the results.

#### 5. Classification

# Box 5: Summary of main DRUID results - CLASSIFICATION (D7.3.2, p. 94-95)

DRUID WP4 proposed four level classification and a labelling system regarding the influence of medicines on driving performance (D4.2.1, D4.3.1):

- category 0: no or negligible influence on fitness to drive (no warning needed);
- category 1: minor influence on fitness to drive (warning level 1);
- category 2: moderate influence on fitness to drive (warning level 2);
- category 3: major influence on fitness to drive (warning level 3).

DRUID WP4 developed a methodology to categorize the influence of medicines on driving performance. The categorization is based on an evaluation of the following issues/steps (D4.3.1):

- conditions of use of the medicine at the European Union market;
- pharmacodynamic and pharmacokinetic data;
- pharmacovigilance data (including prevalence of unwanted effects reported in the SmPC);
- experimental and epidemiological data;
- additional data derived from the Patient Information Leaflet (PIL) and existing categorization systems, and information from other sources;
- synthesis of the available information;
- DRUID categorization and labelling of the psychoactive medicine.

Over 3,000 medicines were reviewed and over 1,500 of them were categorized in regard to their influence on driving performance (D4.3.1, D4.4.1):

- Medicines in the relevant therapeutic groups that are currently on the market have been categorized according to the DRUID classification system (ATC groups: A, B, C, D, N01-N07, M01-M03, R01-R06, S).
- The DRUID project has proposed for analysis and categorization a total of 3,054 medicines from these ATC groups. Of these 3,054 medicines, 1,513 have not been categorized (49,5%), because they are not available on the European Union market.
- The distribution of the 1,541 categorized medicines was as follows: Category 0 50,3%,
   Category I 26%, Category II 11,2%, Category III 5,8%, Multiple category 4,4% and the Depending on the medicine in combination 2,3%.
- Detailed Fact Sheets were elaborated for the N01-N07 (nervous system) and R06 (respiratory system) therapeutic groups of medicines, including information on possible side-effects related to driving, reference studies on psychomotor performance and risk studies, the proposed DRUID categorization level, and relevant information for the patient.

Within DRUID WP4 partners have produced patient-oriented information for each one of the medicines categorized (D4.3.1, D4.4.1).

 The aim of producing this patient-oriented information is to help physicians and pharmacists (and other health professionals) in providing appropriate information to their patients. Although Patient Information Leaflets contain some sort of information regarding driving, DRUID WP4 partners considered that it is also quite important that health professionals provide further information for medicines and driving to their patients.

DRUID WP4 categorization and labelling should be integrated in existing computerized prescribing and dispensing systems for physicians/pharmacists (D7.4.2, D4.3.1).

# Policy implications (D4.2.1, D4.3.1):

- The DRUID WP4 categorization was in line with the recent approved SmPC guidelines adopted in September 2009 (which applies as from 1st of May 2010) by EMA, based on the DRUID WP4 proposal submitted for consideration by the CMD(h), as a response during the consultation phase of the revision of the SmPC guidelines in February/March 2008, proposing that in section 4.7 "Effects on ability to drive and use machines"....., specify whether the medicinal product has a) no or negligible influence b) minor; c) moderate influence or d) major influence on these abilities....
- DRUID results are compatible with any existing national classification system (e.g. FR, ES) and could be integrated in them.
- The following agreements were reached with the PhVWP (recommendations):
  - There is a need to improve information related to effects on driving in the PIL. Information to patients who are advised to use medicines that may impair driving fitness needs to be improved by simple and patient-centred directions based on a clear categorisation system and reflected in the PIL.
  - A basic 2-tier risk categorisation system with standard wordings for the PIL is recommended for medicines without a potential influence on driving fitness (Level 1, reflective of SmPC descriptions; a) no or negligible influence or b) minor influence) and for medicines with a potential relevant influence on driving fitness (Level 2, reflective of SmPC descriptions; c) moderate influence and d) major influence).
  - Clarification of criteria for the evidence in forming the categorisations, as described as a)-d) in the SmPC (section 4.7) into the 2 levels, should be derived in a collaborative effort of DRUID experts and the members of the PhVWP of CHMP, among other partners, preferably with support of EU bodies, such as DG Sanco and DG Move.
  - The development of supplementary information for patients (e.g. warning levels, pictograms) and health care professionals (prescribing and dispensing guidelines), in support of the categorisation system, could be guided with input provided by the DRUID project (D 4.2.1, D 4.3.1, D 7.3.2 and D 7.4.2) as well as by experiences in EU Member States.

# 6. Rehabilitation

# Box 6: Summary of main DRUID results - REHABILITATION (D7.3.2, p. 97-98)

- DUI/DUID rehabilitation helps to prevent people from impaired driving and restores their mobility in a safe way (D5.1.1, D5.2.4).
- DR should be an integrated part of a comprehensive countermeasure system. This should be stated on EU level (D5.1.1, D5.2.4).
- Main outlines of rehabilitation procedures should be formulated on EU level (guidelines for legal regulations and standardised procedure). DRUID WP5 developed Europe-wide standards and recommendations of good practice for DUI/DUID rehabilitation measures, which were couched into the form of a user friendly tool (Development of Driver Rehabilitation Evaluation Tool, DRET) for implementation, assessment or evaluation of existing or new DR systems or programmes. It can be the starting point of a European networking and documentation process of DR measures (D5.2.4).
- Recommendation on assignment to DR (D5.1.1, D5.2.4):
  - Legal regulation of DR participation should be established in order to systematically bring offenders to intervention.
  - A linkage of participation in DR and licensing procedure is considered as important,
     e.g. participation in DR as a precondition for the reduction of the suspension period or for license re-instatement.
  - Formal criteria for directly assigning DUI/DUID offenders to DR (or at least to counselling) should be established in order to initiate problem awareness and screen for a severe alcohol or drug problem. WP5 proposes to use high BAC-level (above 1.6g/L), re-offending within five years, and refusal of test as assignment criteria.
  - Driver assessment prior to DR should be obligatory in case of suspicion of addiction in order to match offenders to appropriate treatment.
  - DR participation should be mandatory for high-risk offenders, repeat offenders and young (novice) drivers.
- Rehabilitation options according to needs of different offenders (D5.1.1, D5.2.1, D5.2.4):
  - Different types of DUI/DUID offenders have different needs and require different types of rehabilitation. The intensity of intervention should increase with the severity of the problem behaviour. Addicted DUI/DUID offenders should be at least separated from non-addicted offenders. If possible DUI and DUID offenders should not be mixed within these groups.
  - European standard group DR interventions (6-12 participants; psychologicaltherapeutic approach with educative elements; led by specially qualified course leader or psychologist respectively) can be recommended as a good practice example for non-addicted DUI/DUID offenders.
  - Information exchange between experts from DR interventions and addiction treatment should be encouraged.
- Quality related requirements of DR (D5.2.3, D5.2.4):
  - The importance of implementation of quality management systems on European, national and driver rehabilitation provider level is stressed.
  - Quality management requirements should be established on a legal base in order to achieve uniform quality management standards. Optimally, these standards are defined on European level.
  - A (national) quality management body should be installed which has an independent, authoritative position to execute the operative quality management tasks in driver rehabilitation.
- Alcohol ignition interlock programmes can be effective for DUI offenders in combination with rehabilitation (D5.1.1, D5.2.4).

#### 7. Withdrawal

# Box 7: Summary of main DRUID results – WITHDRAWAL (D7.3.2, p. 101)

 Regulations in European countries regarding withdrawal and accompanying measures should be unified as far as possible and as far as they do not intervene with other national strategies against DUI/DUID. So far, national strategies are very heterogeneous, hence a clustering of strategies or countries is difficult (D6.2).

#### General recommendations on withdrawal and conditional withdrawal (D6.2.):

- Sanction certainty and celerity are crucial for the general and special deterrent impact of sanctions, above all immediate withdrawal/suspension of driving licence and a high level of perceived detection risk.
- The imposition of driving licence measures shows a higher correlation with the level of deterrence than other sanctions (e.g. imprisonment or fines).
- Withdrawal duration should be set between 3 and 12 months. The deterrent impact of shorter and longer durations has not been proven by empirical primary research; a longer withdrawal period leads in general to an increase in driving without a licence.
- Generally, the combination of withdrawal and rehabilitation/treatment is connected with higher levels of deterrence than the sole imposition of each measure.
- A conditional withdrawal (including a conditional re-instatement of the licence) supports a re-integration process and can be applied if certain requirements are met. Possible conditions are, above all rehabilitative/treatment measures, but also installation of an alcohol ignition interlock and/or regular medical checks.
- DRUID WP6 was not able to conclude on a final recommendation on either administrative or criminal procedure: advantages of an administrative procedure are seen in the sanction celerity and sanction certainty (especially in case of per se legislation); disadvantages of a criminal procedure are related to huge differences in the severity of the imposed sanctions.

#### Further recommendations for specific problem groups (D6.2):

- DUI drivers:
  - A graduated system of withdrawal and additional measures depending on the BAC level - should be introduced.
  - Driver assessment and rehabilitation should be legally regulated and based on defined criteria (see WP5)
  - An alcohol ignition interlock could be offered as an option in exchange for a reduced length of licence suspension and should include at least strict medical counselling or even psychological support.
- DUID drivers:
  - General DUI deterrent principles are also valid for DUID.
  - As long as no threshold values for DUID are defined, driver assessment should always be carried out to assess the fitness to drive and to decide on further rehabilitation/treatment.
- Patients in substitution treatment:
  - Each patient in substitution therapy has to be assessed individually regarding fitness to drive
  - A conditional licence, based on the fitness to drive examination, is recommendable combined with follow-up controls, above all focussing on abstinence of parallel consumption of other drugs.
- Patients in long-term treatment with psychoactive medicines:
  - Legal measures should be taken only after an incident in traffic; impairment is the key indicator for sanctioning.
  - A model of conditional licensing, based on the fitness to drive examination, is recommendable.

# 8. Guidelines and risk communication

# Box 8: Summary of main DRUID results – GUIDELINES/RISK COMMUNICATION (D7.3.2, p. 108)

Reviewing DUI/DUID information and education campaigns (D7.1.1; D7.3.1; D7.3.2):

- The focus of campaigns (content, target group, media etc.) should be selected according to the specific characteristic of problem situation and risk group. The majority of the retrieved campaigns concerned driving under the influence of drugs, aimed at young people (this is not reflecting the actual problem situation) (D7.1.1, D7.3.1).
- Campaigns are more successful if they are targeted (specific issues, groups, etc.). Therefore, large campaigns should be designed as sets of a larger number of activities on a smaller scale (D7.1.1, D7.3.1).
- Campaigns should be evaluated (D7.1.1, D7.3.1).
- Key points for developing and evaluating campaigns have been formulated in the EU project CAST (www.cast-eu.org) (target audience, analysing the situation, message, means and features (media) and communication objectives) (D7.3.1).
- The report at hand is aiming at extracting main DRUID information per target group (general public, young drivers, drivers as patients, physicians and pharmacists and policy makers on EU and national level) based on the theoretic frame of CAST (campaigns) and a more general literature review on risk communication (D7.3.2).

#### Guidelines and professional standards (D7.2.1, D7.4.1):

- Guidelines and standards for health care professionals pertaining to medicines and driving are generally lacking in most European MS (D7.2.1).
- Decision support at the start of a treatment is needed for selecting the least impairing medicines (D7.2.1).
- Eight recommendations on improving the procedures for assessing fitness to drive within the framework of Council Directive 91/439/EEC (on driving licences) have been formulated within DRUID WP7. They aim at 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. These suggestions should be discussed in working groups/expert rounds with physicians, pharmacists, driving licensing authorities and policy makers in order to reach a consensus at European level (D7.2.1).
- Emphasis in <u>prescribing and dispensing guidelines for physicians and pharmacist</u> should be given to shared decision making (health care professional together with the patient) and documentation of patient consultation (to avoid liability issues). Recommendations on the content of prescribing and dispensing guidelines for physicians and pharmacists have been formulated within DRUID WP7. Protocols and guidelines should be integrated in existing computer software used by health care professionals in daily practice (7.4.1).

#### ICT and paper tools for prescribing and dispensing medicines (D7.2.2):

DRUID WP7 developed materials to be used in existing software packages for supporting
integrated application in prescribing and dispensing practices as well as in stand-alone software
packages and paper tools in which risk categorisation and Fact Sheets provided in WP4 are made
accessible for physicians and pharmacists (see also DRUID CD-ROM; D7.2.2).

#### Evaluation on risk communication (D7.4.2; D7.4.3):

- The use of pictograms on medicine boxes for risk communication to patients is effective in explaining a risk of impairment level after using a driving impairing medicine. Patients' likelihood to drive less frequently under the influence of a medicine is higher if the pictogram shows reference to all possible risk levels, and identifies the selected risk level from a rating bar model as compared to a single triangle model without explanation of possible risk levels. Younger patients (more in favour) and older patients (less in favour) differ in their preference for more complex presentations of risk of impairment levels in a pictogram.
- Preliminary evaluation results based on the consolidated database (including common NL, ES and BE results) indicate a positive effect of the DRUID guidelines. Overall, health care professionals are very satisfied with and strongly prefer ICT supporting tools which are integrated in their dispensing/prescribing tools over other supporting tools (D7.4.2).
- Preliminary results of D7.4.3 show that the emphasis should be given to drink driving prevention, targeting the age group 15-24 year. Preventive measures should be differentiated into general preventive approaches (e.g. campaigns) and special focussed preventive measures for certain smaller subgroups (lifestyle types e.g. personal communication). The effectiveness of approaches should be analyzed in-depth based on representative samples (according results for e.g. DE will be available at the end of the DRUID project) (D7.4.3).

# **DRUID Deliverables**

- All deliverables are available on the DRUID homepage (http://www.druid-project.eu).
- D0.1.8: Schulze H., Schumacher M., Urmeew R., Auerbach K. (2011): Final report: Work performed, main results and recommendations. DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 0.1.8
- D1.1.1: Krüger H.-P., Hargutt V., Brookhuis K. (2008): Theoretical framework for substance effects on safe driving. DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 1.1.1
- D1.1.2a: Schnabel E., Hargutt V., Krüger H.-P. (2010): Meta-analysis of empirical studies concerning the effects of alcohol on safe driving. DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 1.1.2a
- D1.1.2b: G. Berghaus G., Sticht G., Grellner W., Lenz D., Naumann Th., Wiesenmüller S. (2010): Meta-analysis of empirical studies concerning the effects of medicines and illegal drugs including pharmacokinetics on safe driving. DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 1.1.2b
- D1.1.2c: Strand M.C., Fjeld B., Arnestad M., Mørland J. (2011): Psychomotor relevant performance: 1. After single dose administration of opioids, narcoanalgesics and hallucinogens to drug naïve subjects 2. In patients treated chronically with morphine or methadone / buprenorphine. DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 1.1.2c
- D1.2.1: Ramaekers J. (2011): The influence of stimulant drugs on actual and simulated driving. DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 1.2.1
- D1.2.2: Ramaekers J. (2011): Effects of medicinal drugs on actual and simulated driving. DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 1.2.2
- D1.3.1: Hargutt V., Knoche A. (2011): Driving under the influence of alcohol, illicit drugs and medicines: Risk estimations from different methodological approaches. DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 1.3.1
- D1.4.1: Krismann M., Schöch H., Knoche A., Hargutt V., Klipp S. (2011): Evaluation of legal measures to combat DUI / DUID. DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 1.4.1
- D1.4.2: Verstraete A., Knoche A., Jantos R., Skopp G., Gjerde H., Vindenes V., Mørland J., Langel K., Lillsunde P (2011): Per se limits Methods of defining cut-off values for zero tolerance. DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 1.4.2
- D2.1.1: Ravera S., De Gier J.J. (2008): Prevalence of Psychoactive Substances in the General Population. DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 2.1.1
- D2.1.2: Bernhoft I. M. (Ed.) (2007): Uniform design and protocols for carrying out case-control studies (Working paper). DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 2.1.2
- D2.1.3: Biecheler M.-B. (2011): Cannabis, driving and road safety: a review of the scientific literature (Working paper). DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 2.1.3
- D2.2.1: Forward S. (2010): Motives behind risky driving driving under the influence of alcohol and drugs. DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 2.2.1
- D2.2.2: Walter M., Hargutt V., Krüger H-P. (2011): Prevalence of psychoactive substances and consumption patterns in traffic, based on a smart phone survey in Germany. DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 2.2.2

- D2.2.3: Part I: Houwing S., Hagenzieker M., Mathijssen R., Bernhoft I. M., Hels T., Janstrup K. Van der Linden T., Legrand S.-A., Verstraete A. (2011): Prevalence of alcohol and other psychoactive substances in drivers in general traffic Part I: General results. DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 2.2.3 Part I
- D2.2.3: Part II: Houwing S., Hagenzieker M., Mathijssen R., Bernhoft I. M., Hels T., Janstrup K., Van der Linden T., Legrand S.-A., Verstraete A. (2011): Prevalence of alcohol and other psychoactive substances in drivers in general traffic Part II: Country reports. DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 2.2.3 Part II
- D2.2.4: Amoros E., Gadegbeku B. and the SAM Group (2010): Prevalence study: Main illicit psychoactive substances among all drivers involved in fatal road crashes in France. DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 2.2.4
- D2.2.5: Isalberti C., Van der Linden T., Legrand S.-A., Verstraete A., Bernhoft I. M., Hels T., Olesen M., Houwing S., Houtenbos M., Mathijssen R. (2011): Prevalence of alcohol and other psychoactive substances in injured and killed drivers. DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 2.2.5
- D2.2.6: Sardi, P. A. (2011): Characteristics of accident involved drivers under the influence: Results from confidential interviews (Working paper). DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 2.2.6
- D2.3.1: Ravera S., de Gier J.J. (2010): Relative accident risk of patients using psychotropic medicines in the Netherlands: A pharmaco-epidemiological study. DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 2.3.1
- D2.3.2: Gadegbeku B., Amoros E. and the SAM group (2010): Relative risk estimates for alcohol and other psychoactive substances impaired drivers in fatal accidents, based on the responsibility approach in France. DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 2.3.2
- D2.3.3: Laapotti S., Keskine E. (2009): Relative risk of impaired drivers who were killed in motor vehicle accidents in Finland. DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 2.3.3
- D2.3.4: Thorsteinsdóttir K., Mühlhäußer J., Paul L., Lottner S., Schick S., Hell W. (2006): Responsibility study: Psychoactive substances among killed drivers in Germany, Lithuania, Hungary and Slovakia. DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 2.3.4
- D2.3.5: Hels T., Bernhoft I. M., Lyckegaard A., Houwing S., Hagenzieker M., Legrand S.-A., Isalberti C., van der Linden T., Verstraete A. (2011): Risk of injury by driving with alcohol and other drugs. DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 2.3.5
- D2.4.1: Bernhoft I. M. (2011): Results from epidemiological research prevalence, risk and characteristics of impaired drivers. DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 2.4.1
- D3.1.1: Cor K. (2009): Evaluation of oral fluid Screening devices by TISPOL to Harmonise European police Requirements (ESTHER). DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 3.1.1
- D3.2.1: Blencowe T., Lillsunde P. (2009): Protocol of "workshop on drug driving detection by means of oral fluid screening. DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 3.2.1
- D3.2.2: Blencowe T., Anna Pehrsson A., Lillsunde P. (2010): Analytical evaluation of oral fluid screening deivces and preceding selection procedures. DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 3.2.2
- D3.3.1: Veisten K., Houwing S., Mathijssen R. (2010): Cost-benefit analysis of drug driving enforcement by the police.DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 3.3.1

- D4.1.1: Pil K., Raes E., Van den Neste T., Goessaert A., Veramme J., Verstraete A. (2008): Review of existing classification efforts. DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 4.1.1
- D4.2.1: De Gier J.J., S. Ravera S., Monteiro S.P., Álvarez F.J. (2011): Establishment of criteria for a European categorisation system for medicinal drugs and driving. DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 4.2.1
- D4.3.1: Gómez-Talegón T., Fierro I., M. Del Río C., Álvarez F.J. (2011): Establishment of framework for classification/categorisation and labelling of medicinal drugs and driving. DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 4.3.1
- D4.4.1: Álvarez F.J. (2011): Classification of medicinal drugs and driving: a synthesis report. DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 4.4.1
- D5.1.1: Boets, S., Meesmann, U., Klipp, S., Bukasa, B., Braun, E., Panosch, E., Wenninger, U., Roesner, S., Kraus, L. & Assailly, J-P. (2008): State of the Art on Driver Rehabilitation: Literature Analysis & Provider Survey. DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 5.1.1
- D5.2.1: Bukasa B., Klipp S., Braun E., Panosch E., Wenninger U., Boets S., Meesmann U., Ponocny-Seliger E., Assailly J-P. (2008): Good Practice: In-Depth analysis on recidivism reasons & analysis of change process and components in driver rehabilitation courses. DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 5.2.1
- D5.2.2: Bukasa B., Braun E., Wenninger U., Panosch E., Klipp S., Escrihuela-Branz M., Boets S., Meesmann U., Roesner S., Kraus L., Gaitanidou L., Assailly J-P. (2008): Development of an integrated evaluation instrument for driver rehabilitation measures. DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 5.2.2
- D5.2.3: Klipp S., Escrihuela-Branz M., Boets S., Meesmann U., Roesner S., Kraus L., Panosch E., Bukasa B., Braun E., Wenninger U., Siegrist S. (2008): Quality management systems established along with driver rehabilitation schemes. DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 5.2.3
- D5.2.4: Bukasa B., Braun E., Wenninger U., Panosch E., Klipp S., Boets S., Meesmann U., Roesner S., Kraus L., Gaitanidou L., Assailly J-P., Billard A. (2008): Validation of existing driver rehabilitation measures. DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 5.2.4
- D6.1.1: Kærup S., Larson L., Godler K., Žlender B. (2009): State-of-the-Art Regarding Withdrawal of Driving Licence in Connection with Sanctions for Impaired Driving Results of Questionnaires. DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme Deliverable 6.1.1
- D6.2.1: Bukasa B., Salamon B., Klipp S., Krisman M., Larsen L., Krašovec B., Merc K., Žlender B., Schnabel E. (2011): Recommendations on Withdrawal. DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 6.2.1
- D7.1.1: Raes E., Pil K., Van den Neste T., Verstraete A. (2007): Task 7.1 Review of guidelines, booklets and other resources: state of the art. DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 7.1.1
- D7.2.1: De Gier J.J., Heissing M., Álvarez F.J., Tant M. (2009): Recommendations for improving medical guidelines for assessing fitness to drive in patients who use psychotropic medicines. DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 7.2.1
- D7.2.2: Monteiro S., De Gier J.J. (2011): Guidelines and Professional Standards. Report + CD or DVD with examples of ICT supported protocols for prescribing and dispensing of medicines affecting driving performance, and for informing patients who use other psychoactive substances than medicines. DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 7.2.2
- D7.3.1: Álvarez F.J., Fierro I., Boets S., Meesmann U., Pil K. (2009): Prototypes of booklets, posters, messages for risk communication including a script for a TV-clip. DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 7.3.1

- D7.3.2: Meesmann U., Boets S., De Gier J.J., Monteiro S., Álvarez F.J., Fierro I. (2011): Main DRUID results to be communicated to different target groups. DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 7.3.2
- D7.4.1: Margaritis, D., Touliou K., Ravera S., Monteiro S., De Gier J. J., Boets S., Meesmann U., Álvarez F.J. (2009): Training Manual for Physicians and Pharmacists on Medicinal drug and Driving. Evaluation and implementation of new technologies. DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 7.4.1
- D7.4.2: Touliou K., Margaritis D., Spanidis P., Monteiro S., Ravera S., De Gier J.J., Boets S., Meesmann U., Tant M. Legrand S.-A., Van der Linden T., Verstraete A., Fierro I., Gómez-Talegón T., Martin L., Álvarez F.J. (2011): Report on the implementation, evaluation and new technologies of practice guidelines and information materials. DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 7.4.2
- D7.4.3: Heißing M., Holte H., Schulze H., Baumann E., Klimmt C. (2011): DRUID outcomes and risk communication to young drivers. DRUID (Driving under the Influence of Drugs, Alcohol and Medicines). 6th Framework programme. Deliverable 7.4.3

# **DRUID** consortium

The DRUID consortium united the following 37 partners from 17 member States and Norway:

##	Participant name	Country
1	Bundesanstalt für Straßenwesen	DE
2	TÜV Rheinland Consulting GmbH	DE
3	Technical University of Denmark	DK
4	Centre for research and technology Hellas	EL
5	National Institute for Transport and Safety Research	FR
6	Université de Caen – Basse Normandie	FR
7	Motor Transport Institute	PL
8	Institute of Forensic Research	PL
9	Universiteit Gent	BE
10	SWOV Institute for Road Safety Research	NL
11	KLPD	NL
12	Maastricht University, Faculty of Psychology	NL
13	University of Groningen, Pharmacy	NL
14	University of Groningen, Psychology	NL
15	Universidad de Valladolid	ES
16	Netherlands Organisation for Applied Scientific Research TNO	NL
17	Statens Väg- och Transportforskningsinstitut	SE
18	Centrum dopravního výzkumu	CZ
19	Centre Regional de Pharmacovigilance	FR
20	Bayerische Julius-Maximilians-Universitaet Wuerzburg	DE
21	Kuratorium für Verkehrssicherheit	AT
22	Jefatura central de trafico	ES
23	Società Italiana di Psicologia della Sicurezza Viaria	IT

##	Participant name	Country
24	Institute of Transport Economics	NO
25	University of Turku	FI
26	Norwegian Institute of Public Health	NO
27	Direkcija Republike Slovenije za ceste <sup>1</sup>	SI
28	National Institute for Health and Welfare	FI
29	Institut Belge pour la Sécurité Routière asbl	BE
30	Ludwig-Maximilians-Universitaet Muenchen	DE
31	Universtaetsklinikum Heidelberg	DE
32	University of Copenhagen	DK
33	Institut für Therapieforschung	DE
34	University of Szeged	HU
35	U.O.C. Tossicologia Forense e Antidoping – Azienda Ospedaliera- Universita di Padova	IT
36	Centre of Post-Graduated Studies in Legal Medicine of the National Institute of Legal Medicine of Portugal	PT
37	Institute of Forensic Medicine, Mykolas Romeris University	LT
38	Javna agencija Republike Slovenije za varnost prometa	SI

-

<sup>&</sup>lt;sup>1</sup> As of 31.08.2010 Javna agencija Republike Slovenije za varnost prometa (AVP) took over rights and responsibilities of the DRSC. For administrative reasons, DRSC stayed an official partner following Commission's request. Thus, AVP became the 38s DRUID partner.

# **DRUID** implementation structure

DRUID was structured objective oriented and aiming to address the following requests of the European Commission:

EC requirements	Work package	Work package content description
To enable policy makers to refer to a substance blood concentration threshold defined for driving a power-driven vehicle	WP 1	Methodology and Experimental Research
To deliver reference studies of the impact on fitness to drive for alcohol, illicit drugs and medicines	WP 2	Epidemiological Studies, Relative Risk Calculation
To evaluate mobile drug detection devices and to implement cost-benefit analysis of enforcement strategies	WP 3	Enforcement: Methods and Devices, Enforceable Legislation
To introduce classification and labelling system for medicines with regard to their influence on driving performance	WP 4	Developing a Classification System for Medicinal Drugs
To provide authorities with recommendations concerning effective drivers rehabilitation schemes, adapted to individual driver's situation	WP 5	Rehabilitation – Good Practice
To recommend strategies of driving bans, which are compatible with the road safety objectives and at the same time respect the need for mobility	WP 6	Withdrawal – Existing Practices and Recommendations
To define responsibility of health care professionals vis-à-vis dangerous patients consuming psychoactive substances and the role they can play with regard to road safety. To develop information and dissemination instruments for different target groups	WP 7	Dissemination and Guidelines, Training Measures