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Driving Under the Influence of Drugs, Alcohol and Medicines in Europe — findings from the DRUID project

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European Monitoring Centre
for Drugs and Drug Addiction

THEMATIC PAPERS

Driving Under the Influence of Drugs, Alcohol and Medicines in Europe — findings from the DRUID project

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This report has been prepared by Brendan Hughes and Liesbeth Vandam of EMCDDA. It does not reflect the official position of the European Commission.

Foreword

We are pleased to present the key findings of the European Union's research project on Driving Under the Influence of Drugs, Alcohol and Medicines, known as the DRUID project. The project was set up by the European Commission's Directorate-General for Energy and Transport and comprised seven work packages: experimental studies, epidemiological studies, enforcement, classification (of medicines), rehabilitation, withdrawal (of driving licence), and dissemination and guidelines. Over 5 years of work across 18 countries, the project has produced some 50 reports, each one contributing key evidence to road safety policy.

This thematic paper has been prepared by the EMCDDA with the DRUID project coordinator and work package leaders, and is based on the project's reports and findings. By publishing this paper, the EMCDDA aims to bring the main results of the DRUID project to a wider audience.

The EMCDDA is proud to be associated with this seminal work and, although the project itself is now complete, wishes to support its legacy and its peerless contribution to common European standards in drug-driving research. We would like to thank all DRUID partners and especially the work package leaders for their important contribution to the project's success, and also the peer reviewers whose expert knowledge enhanced the quality of the deliverables. It would not have been possible to complete this project without the support and close collaboration of the European Commission and especially that of the project officers Joel Valmain and Maria-Cristina Marolda.

We believe the findings of this project will contribute to enhancing the safety of citizens on the roads of Europe, today and in the future.

Wolfgang Götz
Director, EMCDDA

Horst Schulze
DRUID project coordinator

Summary

Roadside surveys conducted in 13 countries across Europe, in which blood or oral fluid samples from 50 000 drivers were analysed, revealed that alcohol was present in 3.48 %, illicit drugs in 1.90 %, medicines in 1.36 %, combinations of drugs or medicines in 0.39 % and alcohol combined with drugs or medicines in 0.37 %. However, there were large differences among the mean values in the regions of northern, eastern, southern and western Europe. Although the absolute numbers were quite low, the prevalence of alcohol, cocaine, cannabis and combined substance use was higher in southern Europe, and to some extent in western Europe, than in the other two regions, whereas medicinal opioids and 'z-drugs', such as zopiclone and zolpidem, were detected more in northern Europe.

Studies of hospitalised, seriously injured car drivers were conducted in six countries, and studies of car drivers killed in accidents took place in four countries. Among the injured or killed drivers, the most commonly consumed substance was alcohol alone, followed by alcohol combined with another substance. The use of illicit drugs alone was not frequently detected. After alcohol, the most frequently found substance among injured drivers was tetrahydrocannabinol (THC) followed by benzodiazepines, whereas, among drivers killed in accidents, it was benzodiazepines.

The results of the roadside surveys and the hospital surveys were combined in a case–control study to calculate the relative risk of being seriously injured or killed in a traffic accident. The project assigned the investigated substances to one of four groups, according to whether the increased risk was considered to be slight, medium, considerable or high. The findings showed that alcohol is still one of the most dangerous psychoactive substances used by drivers. The biggest risk for a driver of being seriously injured or dying in a traffic accident arises from high blood alcohol levels or from combinations of alcohol, drugs or medicines.

Most of the seriously injured or killed drivers who tested positive for alcohol were severely intoxicated. However, results of interviews in two countries showed that problem drinkers do not believe that alcohol impairs their driving. Intensive drug users were more likely than moderate drug users to drive under the influence, with the latter taking a more responsible approach to driving under the influence of drugs.

Alcohol and drugs were detected more often in male drivers. Medicines were detected mainly in middle-aged and older female drivers, but, among drivers seriously injured or killed in accidents, medicines were more often found in male drivers in the same age ranges, often in combination with other substances.

Experimental studies suggested that the illicit stimulants d-amphetamine, MDMA ('ecstasy') and cocaine have no negative influence on fitness to drive, but studies of drivers injured and killed in accidents found considerably higher median drug levels for stimulants, and such levels may have detrimental effects on self-perception, critical judgement and risk-taking. A night of sleep deprivation alone impairs performance to a similar degree to the 0.8 g/l blood alcohol concentration (BAC), i.e. higher than the common legal driving limit of 0.5 g/l, and MDMA in combination with alcohol (or sleep deprivation) causes dramatic impairment of driving

performance; stimulants do not compensate for alcohol use or sleep deprivation. A few medicines can cause impairment of which the patient is unaware.

A number of recommendations were made to update the wording of the 1991 European Council Directive on Driving Licences, referring to licence withdrawal due to consumption of drugs and psychoactive substances.

Very few public information campaigns regarding drug-driving were evaluated for their impact — and some of them evaluated only awareness of the campaign, rather than if it changed driver behaviour.

Psychoactive medicines on the EU market were classified into four categories depending on their influence on fitness to drive, and it was demonstrated that a pictogram on the package indicating the risk when driving was effective in changing patients' intended behaviour. In collaboration with experts of the Pharmacovigilance Working Party of the European Medicines Agency, recommendations could be presented for improving the package information leaflet for category II (moderately impairing) and category III (severely impairing) medicines. It was also shown that a software package could assist physicians and pharmacists in giving advice to patients when prescribing and dispensing such medicines, respectively.

Legal limits, consistently enforced, are the single most effective approach to combat drink-driving. The maximum standard legal limit should be 0.5 g/l BAC, and stricter limits for certain risk groups (novice drivers, professional drivers) should be considered. As mixed intoxication with other substances poses a greater risk, the alcohol limit must be lower in such cases.

To combat drug-driving, most countries either operate a zero tolerance policy or take into account degree of impairment, sometimes in a two-tier system. Legal limits may be set low, at the limit of detection, or higher to take effects into consideration. For example, while the project set a detection limit of 1 ng/ml in whole blood for THC in the roadside surveys, it was found that 2 ng/ml THC in whole blood (3.8 ng/ml THC in serum) seems to cause impairment equivalent to 0.5 g/l BAC. Such equivalents could not be calculated for other drugs. It is not realistic to develop cut-off limits for all substances.

Regarding driving under the influence of medicines, a legal limit for patients undergoing long-term treatment is inappropriate; sanctions should be based on degree of impairment.

None of the roadside oral fluid testing devices achieved the target value of 80 % sensitivity, specificity and accuracy for all the individual substances tested. Thus, when considering the suitability of a device, the type and prevalence of drugs within the target population should be considered. An evaluation of a checklist of clinical signs of impairment, such as bloodshot eyes, did not give promising results; more experience and better training of police officers may improve this.

In the near future, analysis of dried blood spots could be a much quicker and less invasive method of proving an offence than taking a sample of whole blood from a driver using a syringe. Transport and storage of dried blood spots are also much easier than for whole blood.

A cost–benefit evaluation found that increased enforcement of drug-driving sanctions, based on roadside oral fluid screening, is potentially cost-beneficial, particularly for countries where the level of enforcement is currently low. However, increasing drug-driving enforcement at the expense of a reduction in drink-driving enforcement may actually decrease the positive impact on road safety. As the risk and share of injuries is higher for alcohol, targeting driving under the influence of alcohol should always be the first priority of law enforcers.

Withdrawal of the driving licence is an effective deterrent and sanction, more so than prison or fines, but only when it is implemented quickly and for a period of 3–12 months (longer leads to non-compliance). Combining licence withdrawal with rehabilitation/treatment is more effective than licence withdrawal alone. Withdrawal of the licence of patients undergoing long-term treatment, including substitution treatment, should be based on an individual assessment of a patient's fitness to drive overall, not simply on substance consumption.

Some driver rehabilitation schemes can reduce recidivism by an average of 45 %. Drivers with addiction or similar problems are unlikely to benefit from a rehabilitation programme and should be matched to more appropriate treatment. Rehabilitation options should vary according to the needs of different offenders.

Introduction

Across the current 27 Member States of the European Union (EU-27), 75 426 people lost their lives in road traffic accidents in just one year: 1991. Ten years later, by 2001, that annual toll had been reduced to 54 302. With this in mind, the EU's Third Road Safety Action Programme 2003–10 set the ambitious objective of halving the number of road deaths in the EU by 2010, down to about 27 000 in the EU-27. This target was not quite met, but the number of fatalities declined steadily over the period, reaching 31 029 in 2010 ([1]).

At the start of the 2003 Action Programme, it was estimated that about 25 % of fatalities on European roads were due to the influence of alcohol, but a lack of comparable studies meant that the proportion due to the effects of illicit drugs or psychoactive medicines was unknown. In the 1990s, increased knowledge of the levels of illicit drug use among the general population was one of the factors that provoked interest in quantifying illicit drug use among drivers. However, the first attempts to estimate how many people were driving under the influence of psychoactive substances found that licit psychoactive medicines accounted for a higher proportion of drug-driving than illicit drugs. The issue is further complicated by the fact that some people take psychoactive medicines for recreational rather than therapeutic purposes.

Since the mid- to late 1990s, many studies have been carried out in an attempt to determine the level of drug-driving on European roads ([2]). However, these studies suffer from the use of different parameters and so the results are not comparable. A study in which drivers are tested at random in a small town on a Tuesday morning might find a prevalence of drug-driving of 0.5 %, whereas a study carried out on a Saturday night on a road leading to/from the nightclub district of a major city, and stopping only those vehicles being driven erratically, might find that 50 % of drivers test positive for drugs. There is similar scope for diversity in the definition of a 'positive' test. A study that considers the smallest trace of a substance in urine (in which metabolites can be detected for longer than blood) as 'positive' will result in considerably higher prevalence rates than one that records only those drivers in whom drugs are found in blood, above a high value that has been calculated as 'equivalent' to impairment by alcohol. In a large study, matters are complicated by the fact that different toxicological laboratories have different equipment, and so one will report a sample as 'positive' when another would report the same sample as 'negative'. Non-standardised studies of the situation preclude any meaningful evaluation of the effectiveness of the various responses and countermeasures.

For this reason, the DRUID (Driving Under the Influence of Drugs, Alcohol and Medicines) project was established, with the aim of estimating the size of the problem and examining the range of appropriate countermeasures.

As the DRUID project was being drawn up, the Working Group on Illegal Drugs and Driving, attached to the International Conference on Alcohol, Drugs and Traffic Safety, which meets approximately every 3 years ([3]), recommended that a consensus meeting of international drug-

([1]) http://ec.europa.eu/transport/road_safety/pdf/observatory/historical_evol.pdf
([2]) EMCDDA Insights 8: http://www.emcdda.europa.eu/publications/insights/driving
([3]) http://www.icadts.org/

driving researchers (toxicologists, epidemiologists, behavioural scientists, trauma specialists, police, etc.) should develop standards to serve as a basis for future research. Such guidelines could enable researchers to harmonise the design of future experiments and encourage collection of data on core standardised variables that would facilitate cross-study comparisons. The meeting was held in September 2006 in Talloires, France, and was attended by key experts who would be involved in the DRUID project, as well as experts from the United States and Australia ([4]). In this way, as the DRUID project launched, its protocols were already taking into account the various challenges involved in achieving international comparability.

The project ran for 5 years and involved 38 consortium partners from 17 Member States and Norway. The total cost was EUR 23 933 860, and the EC contribution was EUR 18 932 265. The 50 full reports of this project (the project 'deliverables') are available on the project website and run to several thousand pages (see Annex 2). This thematic paper, therefore, aims to summarise the findings of one of the biggest and most important research projects ever carried out in the EU on drugs and driving.

([4]) http://onlinelibrary.wiley.com/doi/10.1111/j.1360–0443.2008.02277.x/full

Part A: Understanding the problem

The DRUID project aimed to quantify the size of the drink- and drug-driving problem in Europe by estimating the number of individuals who would test positive for substance use in each participating country, and to determine whether the prevalence of drug-driving has any link with the prevalence of drug and medicine use in the population in general. Data obtained from various national studies, among others roadside surveys in 13 countries, were used to draw up a profile of the 'typical' substance-positive driver. Studies based on information from hospitals on drivers seriously injured or killed in road traffic accidents gave the percentage of these drivers tested positive for psychoactive substances. A comparison of information on the prevalence of substances in the injured drivers, the so-called 'cases', with information on the prevalence of substances in the driving population, the so-called 'controls', allowed estimation of the magnitude of the increased risk of being seriously injured or killed when driving while positive for various substances. This major epidemiological work was supplemented by results from experimental behavioural studies in which drivers were observed and tested under controlled conditions.

How common is drink- and drug-driving in Europe?

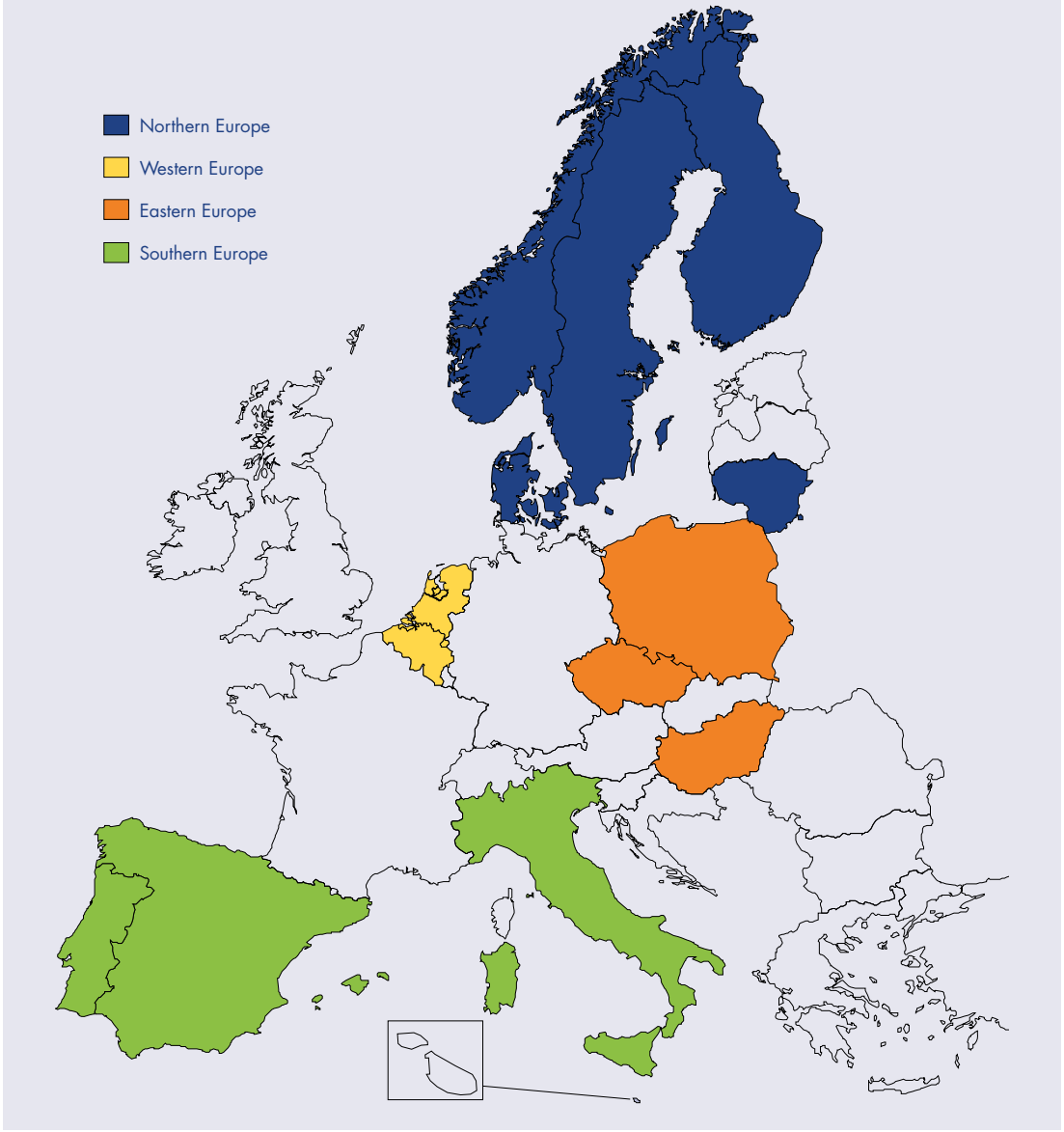
The prevalence of alcohol and other drug use in the driving population was assessed in 13 European countries (Belgium, the Czech Republic, Denmark, Spain, Italy, Lithuania, Hungary, the Netherlands, Poland, Portugal, Finland, Sweden, Norway) based on the results of roadside surveys carried out between January 2007 and July 2009. According to the United Nations geoscheme, which divides Europe into regions ([5]) and limiting 'Europe' to the EU and Norway, these 13 countries account for 89 % of the population of southern Europe and 63 % of the population of eastern Europe, but only 29 % of the population of northern Europe (as no survey took place in the United Kingdom) and 11 % of the population of western Europe (as no surveys took place in France or Germany). Therefore, care should be taken in extrapolating any of these outcomes to a pan-European level. Detailed results can be seen in the table in Annex 1.

To ensure that results between countries were comparable, the DRUID project established common parameters for its roadside surveys. Drivers of passenger cars and vans were randomly selected using a stratified multistage sampling design. Regions were selected to be representative of the country with regard to substance use and traffic distribution. Within these regions, drivers in selected survey locations were stopped at random and asked to participate in the study ([6]).

([5]) http://unstats.un.org/unsd/methods/m49/m49regin.htm#europe

([6]) When participation in epidemiological studies is voluntary, as in this case, non-response and non-response bias are common problems. Non-response bias occurs when non-respondents differ from respondents with regard to drug and/or alcohol use. As the drug tests were mandatory only in Italy, researchers in other countries had to take into account non-response rates. If drivers under the influence of drugs and/or alcohol were more likely than non-users to refuse to participate, the results of the roadside surveys would underestimate the prevalence of psychoactive substance use. In this case–control study, underestimation of the prevalence among controls would result in overestimation of the risk associated with psychoactive substance use. In order to exclude a selective non-response bias, the response and non-response group were compared in terms of other variables to determine their degree of similarity.

Figure 1. Geographical distribution of DRUID roadside surveys, according to United Nations geoscheme



The study population sample was stratified into eight time periods covering all the days of the week and all times of the day ([7]). In three countries (Belgium, Italy and the Netherlands) both blood and oral fluid were collected, in Lithuania only blood was collected, and in the remaining nine countries only oral fluid was collected. All countries used a StatSure Saliva

([7]) The study population was not necessarily representative of the general driving population during the selected sampling periods because in many of the 13 countries sampling periods researchers were required to take into account the preferences of the police, who were needed to stop drivers in moving traffic. Weighting factors were applied to correct for this disproportion, based on the ratio by time period between the distribution of traffic and the distribution of the participants.

Sampler device for oral fluid collection, except the Netherlands, where oral fluid was collected in ordinary spit cups ([8]).

The substances under investigation were also standardised. A total of 23 substances, including ethanol (alcohol), were initially included in the 'core substance list'. Three substances that most partners also included in their analyses were later added; the final core list of substances can be found in Annex 2. Some other frequently used psychoactive medicines, such as antidepressants, 'first-generation' antihistamines, anti-epileptics and antipsychotics, were not included in the 'core substance list' by consensus, although some individual countries did choose to test for these substances. Some metabolites of the most common drugs were also included on the list, either as the original drug cannot be detected in the body (e.g. 6-AM as an indicator of heroin use) or as they had already been established as core analytes in other driver surveys (e.g. THC-COOH (carboxy-THC) from THC and benzoylecgonine from cocaine).

All samples were confirmation analysed by toxicological laboratories. In order to achieve agreement on what would be recorded as a 'positive' result, an analytical cut-off (limit) was set for each substance. This cut-off was initially based on the lowest detectable quantity, the 'limit of quantification' (LOQ), but this is different in each toxicological laboratory owing to the use of different instruments and procedures. To ensure that results were comparable, analytical cut-offs were chosen that could be measured by all laboratories for each of the core substances.

However, some substances are found at much higher concentrations in oral fluid than in blood, whereas in the case of other compounds the opposite is true. For example, one of the main metabolites of cannabis, THC-COOH, is not detectable in oral fluid when it is detectable in blood, as its concentrations in oral fluid are extremely low (pg/ml); thus an oral fluid test result would be registered as negative, when a blood test of the same driver would be registered as positive. For this reason in particular, THC-COOH was excluded from the final list of recommended test substances. For other substances for which the difference was not so great, studies were conducted to calculate equivalent cut-off concentrations (above the analytical cut-offs) for blood samples and oral fluid samples taken with the StatSure saliva sampler. The agreed equivalents would then be used to categorise a sample as positive or negative. Such equivalent concentrations have not previously been calculated between whole blood and oral fluid, and thus they constituted an important outcome of this study, solving the problem of two different sample types being collected in roadside surveys. When both an oral fluid and a blood sample were taken from a driver, the result of the blood analysis was given preference.

In total, over 50 000 car and van drivers in the 13 participating countries provided an oral fluid sample, a blood sample or both. This permitted estimation of the current prevalence of alcohol and other drugs in the driving population across a large part of Europe.

Alcohol was the psychoactive substance most frequently detected in the general driving population. The results were broken down into those above the agreed analytical cut-off in blood, those above

([8]) In popular discussion, the word 'saliva' is often used to mean 'oral fluid'. Strictly speaking, 'saliva' is the fluid collected from a specific salivary gland and is free from other materials. 'Oral fluid' is the saliva from the various salivary glands, mixed with other constituents present in the mouth. https://www.ncjrs.gov/pdffiles1/nij/grants/203569.pdf

the common legal blood alcohol content (BAC) of 0.5 g/l, and those above the common legal definition of severe intoxication of 1.2 g/l BAC. The results can be summarised as follows:

Blood alcohol content	Weighted mean across 12 countries ([1])	Range
≥ 0.1 g/l	3.5 %	0.15 – 8.59 %
≥ 0.5 g/l	1.5 %	0.07 – 5.23 %
≥ 1.2 g/l	0.4 %	0.01 – 1.47 %

([1]) No alcohol results were available for Sweden. Alcohol-positive drivers (over 0.2 g/l) were dealt with by the police and so did not take part in the survey.

The prevalence of illicit drugs in the general driving population, though varying widely between the different countries, was much lower than that of alcohol:

Illicit drug groups	Weighted mean across 13 countries	Range
All drugs	1.9 %	0.2 – 8.2 %
THC	1.32 %	0.0 – 5.99 %
Cocaine	0.42 %	0.0 – 1.45 %
Amphetamines	0.08 %	0.0 – 0.38 %
Illicit opioids	0.07 %	0.0 – 0.3 %

THC was the illicit drug most frequently detected in drivers, followed by cocaine. Amphetamines and illicit opioids were less frequently detected.

The prevalence of some frequently used psychoactive medicines (benzodiazepines, medicinal opioids, and 'z-drugs' such as zopiclone and zolpidem) in the driving population across Europe was, on average, lower than the prevalence of alcohol and illicit drugs:

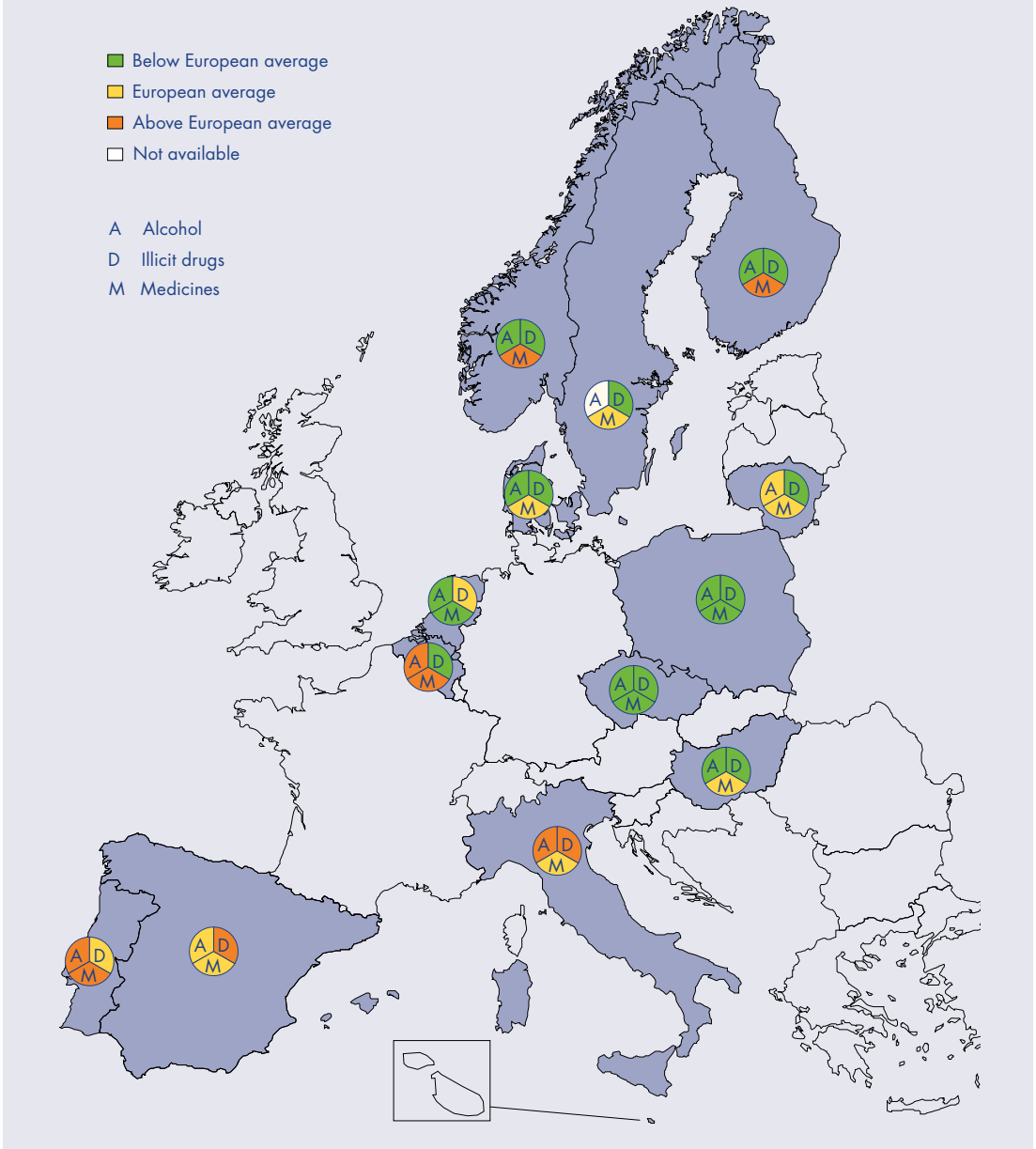
Medicine groups	Weighted mean across 13 countries	Range
All medicines	1.4 %	0.17 – 2.99 %
Benzodiazepines	0.9 %	0.14 – 2.73 %
Medicinal opioids	0.35 %	0.00 – 0.79 %
Z-drugs	0.09 %	0.00 – 0.69 %

Benzodiazepines were the most often detected medicine in drivers, with medicinal opioids and z-drugs less common. Once again, prevalence varied greatly between the different countries.

Combinations of alcohol, illicit drugs and medicines were not included in the above figures, but recorded separately, as follows:

Combinations	Weighted mean across 13 countries	Range
Alcohol with drugs and/or medicines	0.37 %	0.00 – 1.14 %
Combinations of drugs and/or medicines	0.39 %	0.00 – 1.22 %

Figure 2. Distribution of alcohol, illicit drugs and medicines found in car drivers in 13 European countries



In summary, the highest prevalence was found for alcohol, more frequently in drivers in the southern countries of Europe. Regarding medicines and illicit drugs, there was a tendency towards greater use of medicines by drivers in the northern countries and greater use of illicit drugs by drivers in the southern countries.

The use of alcohol, illicit drugs, and medicines was relatively low in most of the eastern countries compared with the other European regions whereas drug use by drivers in the two western European countries was more or less on a parallel with the European average.

Combined use of alcohol and drugs and multiple drug/medicine use were more common in drivers in the southern region. After alcohol, the substances most commonly used in combinations were THC, cocaine and benzodiazepines.

A study to determine national rates of drug and medicine consumption in the general population found that, across Europe, there is a tendency for the consumption in the driving population to reflect the consumption in the whole population, i.e. the prevalence of medicines is relatively higher in the Nordic countries and the prevalence of illicit drugs use is comparatively higher in the southern countries of Europe. However, it would not be correct to assume that, just because there is a high rate of substance use among the general population of a country, a similarly high rate would be found in the driving population.

The details of the research and findings can be found in the deliverables from Work Package 2 — see Annex 3.

How often are psychoactive substances found in drivers seriously injured or killed in road traffic accidents?

A cross-sectional survey was conducted to determine the prevalence of alcohol and other drugs in drivers seriously injured (sampled between October 2007 and May 2010) or killed (sampled between January 2006 and December 2009) in road traffic accidents in nine European countries. Studies of hospitalised, seriously injured, car drivers were conducted in six countries (Belgium, Denmark, Italy, Lithuania, the Netherlands, Finland); studies of car drivers killed in accidents took place in four countries (Portugal, Finland, Sweden, Norway). Once again, a uniform study design was developed for all participating countries. Obligatory inclusion criteria were as follows: driver of a motorised vehicle; injured in an accident on a public road or in the direct vicinity of a public road; primary admission to the hospital only (no referrals), for trauma-related reasons, with a time interval between the accident and sampling of less than 3 hours; and a MAIS (Maximum Abbreviated Injury Scale) score of 2 or higher. For those counted as killed drivers, the time between accident and death was a maximum of 24 hours. Each country could decide upon additional national criteria. Finally, the study considered the relatively similar subpopulations of passenger car and van drivers, and so the results are compiled from 2 492 drivers seriously injured and 1 118 drivers killed in road traffic accidents.

Alcohol was the substance most frequently detected in drivers seriously injured or killed:

	Range (seriously injured)	**Range (killed)**
Alcohol	14.1 – 30.2 %	15.6 – 38.9 %

The highest percentage of seriously injured drivers who tested positive for alcohol was found in Belgium, whereas the highest percentage of drivers killed in accidents who tested positive for alcohol was found in Portugal. Overall, 24.4 % of the injured driver population and 31.7 % of the killed driver population tested positive for alcohol. Of those injured and killed drivers who tested positive for alcohol, 70 % were severely intoxicated, with BAC ≥ 1.2 g/l.

The use of illicit drugs among drivers seriously injured or killed varied between the countries. The use of illicit drugs alone was not frequently detected among drivers injured or killed in Europe, as visible in the following table; in the majority of cases, illicit drugs were found in combination with other psychoactive substances, mainly alcohol. THC (and/or THC-COOH) seemed to be one of the most prevalent illicit drugs, followed by cocaine and amphetamines:

Illicit drug groups	Range (seriously injured)	Range (killed)
THC (and/or THC-COOH)	0.5 – 2.2 %	0.0 – 1.8 %
Cocaine (and/or benzoylecgonine)	0.0 – 1.3 %	0.0 – 0.0 %
Amphetamines	0.0 – 1.1 %	0.0 – 2.1 %
Illicit opiods	0.0 – 0.7 %	0.0 – 0.0 %

The highest percentage of seriously injured drivers found to be cannabis positive was in Belgium and the lowest in Lithuania. The highest percentage of drivers killed in accidents who tested positive for cannabis was in Norway and the lowest was in Finland. Amphetamine use appeared to be more common in northern Europe. No drivers killed in accidents in Portugal tested positive for amphetamines. Cocaine use seemed to be more common in southern Europe than elsewhere. In Finland no drivers seriously injured or killed tested positive for cocaine. No illicit opioids were found in the drivers killed in accidents.

Regarding medicines, the findings among drivers injured and killed were as follows:

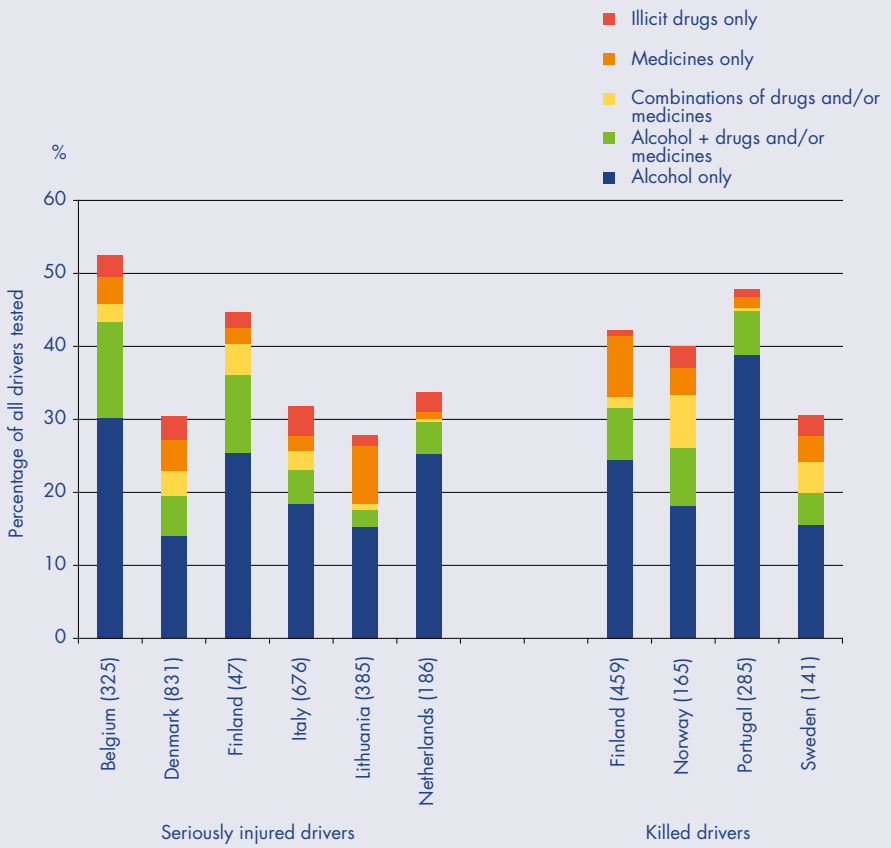
Medicine groups	Range (seriously injured)	Range (killed)
Benzodiazepines	0.0 – 2.3 %	0.0 – 5.2 %
Medicinal opioids	0.0 – 5.7 %	0.6 – 1.5 %
Z-drugs	0.0 – 2.1 %	0.0 – 2.8 %

Among injured drivers, the most frequently found substances after alcohol and THC were benzodiazepines, whereas, among drivers killed in accidents, benzodiazepines were second only to alcohol, followed by amphetamines. Benzodiazepine use appears to be more common in northern Europe, in drivers both seriously injured and killed, with the highest proportion of positive tests in both categories found in Finland. In the Netherlands no seriously injured drivers tested positive for benzodiazepines. Z-drug use was found only in northern Europe; no positive findings were recorded in Italy, Lithuania or Portugal. Medicinal opioids were found in all countries, with the greatest use in seriously injured drivers in Lithuania and the lowest use in the Netherlands. In Sweden, the percentage of drivers killed in accidents who tested positive for medicinal opioids was twice that found in Portugal, Finland or Norway.

Regarding combinations of substances, the findings among drivers injured and killed were as follows:

Combinations	Range (seriously injured)	Range (killed)
Alcohol with drugs and/or medicines	2.3 – 13.2 %	4.3 – 7.9 %
Combinations of drugs and/or medicines	0.5 – 4.3 %	0.4 – 7.3 %

Figure 3. Distribution of psychoactive substances found in seriously injured or killed drivers



Among drivers seriously injured or killed, the most commonly consumed substance was alcohol alone, followed, in all countries except Lithuania, by alcohol combined with another substance. Combined drug/medicine users were either the third (in Belgium, Denmark, Italy and Finland) or fourth (in Lithuania and the Netherlands) most common group. Thus, the biggest problem with illicit drugs is their consumption in combination with other psychoactive substances, especially alcohol. Although the rates of combined consumption were not high, the risk of injury is clearly increased in these cases.

The details of the research and findings can be found in the deliverables from Work Package 2 — see Annex 3.

Who is the 'average person' found driving after taking psychoactive substances?

Data collected during the roadside surveys allowed a description to be drawn of the 'average driver' testing positive for the different substance groups. These included younger drivers (in the age range 18–34 years), middle-aged drivers (35–49 years) and older drivers (≥ 50 years).

Characteristics of drivers testing positive for alcohol

Among the general driving population, alcohol was most often detected among male drivers over 35, BAC values were relatively low (9) and most positive tests were recorded on weekday nights and at weekends. Among drivers involved in accidents, alcohol was most often detected among younger male drivers (25–34 years) and the mean BAC level was high; most were severely intoxicated.

Interviews with problem drink-drivers in Hungary and Sweden found that drivers do not believe that alcohol impairs their performance. Problem alcohol users who drank and drove stated that losing their licence or even imprisonment would not have helped them to stop reoffending; instead, they claimed that a subsequent treatment programme had helped them by giving them a greater insight into their problems.

Characteristics of drivers testing positive for illicit drugs

Among the general driving population, illicit drugs were mainly detected among young male drivers, and at all times of the day but mostly at the weekends. However, the most frequent time period differed according to country, and the user profile differed according to substance. Cannabis and cocaine were most prevalent among young male drivers (in the age ranges 18–34 years and 25–34 years, respectively). Amphetamines were most prevalent among young drivers (18–34 years), but the gender distribution differed according to country. Illicit opioids were most prevalent among male middle-aged drivers (35–49 years). The highest prevalence of the combined use of alcohol and drugs (illicit drugs and/or psychoactive medicine) was generally found in young male drivers (18–34 years) during night-time hours. Multiple drug use (illicit drugs and/or psychoactive medicines) was generally most common in males, and in middle-aged drivers (under 50), although age groups and time periods varied considerably by country.

The studies of drivers seriously injured or killed found that illicit drugs were most prevalent in young and middle-aged drivers (under 50 years), usually male, and the majority of drugs appeared to be used in combination with other psychoactive substances (mainly alcohol).

Interviews with Swedish drivers who were problem drug users revealed that they did not believe that they would be stopped by the police, or that alcohol or drugs would impair their driving, and therefore they did not perceive any real risks in driving. A survey of 195 German drug-using drivers found that intensive users did not feel impaired, even though they were, and were more likely to drive under the influence, whereas moderate substance users could realistically judge their level of intoxication and took a more responsible approach to drugs and driving, choosing to drive less often or not at all after taking drugs.

Characteristics of drivers testing positive for psychoactive medicines

In the general driving population, psychoactive medicines, both benzodiazepines and medicinal opioids, were mainly detected among middle-aged and older female drivers (≥ 35 years) during daytime hours. However, the studies of the drivers seriously injured or killed found these substances

(9) Except in Lithuania, where 38 % of drivers testing positive for alcohol alone had a BAC of over 1.2 g/l.

to be more prevalent in male drivers in the same age range, and the majority were detected in combination with other psychoactive substances (alcohol or drugs).

The details of the research and findings can be found in the deliverables from Work Package 2 — see Annex 3.

What do experiments show regarding the effects that different substances have on driving ability?

In addition to considering large-scale studies of the numbers of drivers seriously injured or killed, the effects of the substances were also gauged using both meta-analyses of previously published experimental studies and 13 driving tests on public roads or using driving simulators involving different substances or their combinations and different participant groups (patients or drug users as appropriate).

Meta-analyses of experimental studies

The meta-analysis of experimental studies of alcohol considered 450 published papers in which 5 300 findings concerning alcohol effects were included. These results allowed calculation of an impairment function that could then be used to determine the concentration of psychoactive substances causing the same level of impairment as certain BAC levels.

The meta-analysis of experimental studies of medicines and illicit drugs considered 605 publications. This meta-analysis provided information about the impact of antipsychotics, anxiolytics, hypnotics, sedatives, antidepressants, antihistamines and major illicit drugs on driving and skills related to driving. It found that a few anxiolytics, antidepressants and sedatives and one antipsychotic caused considerable impairment at certain doses, as did oral administration of THC (e.g. consumption in cake, tea). Neither antihistamines nor illicit drugs (even THC from smoking cannabis) caused comparable impairment. A significant finding from the meta-analysis was that a serum concentration of 3.8 ng/ml THC (≈ 2 ng/ml in whole blood) was shown to be as impairing as 0.5 g/l BAC. In the experimental studies analysed, no negative influence on fitness for driving was found for the illicit stimulants d-amphetamine, MDMA and cocaine; in general, there were more findings of improved performance than of impaired performance. However, some case reports and non-experimental publications examining cocaine revealed negative effects.

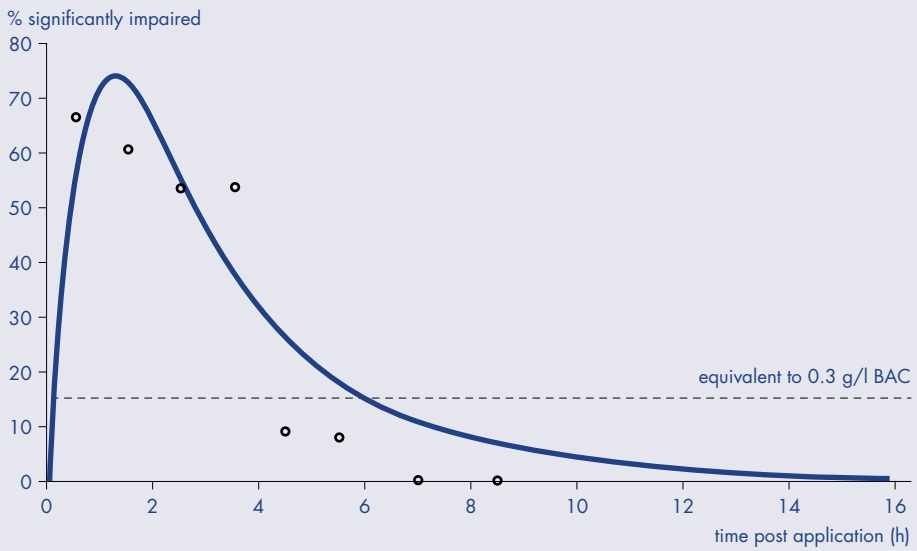
The maximal impairment of a substance is an important parameter in estimating the danger associated with use of that substance; however, maximum impairment may be of short or long duration. Therefore, for each substance that had been the subject of sufficient experimental studies, the project used the impairment function to construct an impairment curve, showing the degree of impairment over time. Once the curve was constructed, the 'area under the curve' was calculated to capture both the level of impairment and the duration. To exclude minor effects, a line was drawn to represent impairment equivalent to 0.3 g/l BAC. The final measure of the danger of a substance, the 'degree of impairment', indicates the area between the approximation curve and the minor impairment line, thus capturing in a single parameter both the intensity (magnitude of impaired effects) and duration of impairment (see Figure 4).

Table 1. Degree of impairment sorted in ascending order within the different substance classes

Class	Substance/Dose [mg]	Degree of impairment
Anxiolytics	Buspirone (10)	0
	Buspirone (20)	0
	Clobazam (10)	0
	Clobazam (20)	0
	Meprobamate (400)	0
	Meprobamate (800)	0
	Diazepam (5)	17
	Diazepam (10)	57
	Lorazepam (1)	64
	Oxazepam (15)	104
	Diazepam (15)	112
	Oxazepam (30)	170
	Diazepam (20)	171
	Alprazolam (1)	369
	Lorazepam (2)	418
	Lorazepam (2.5)	571
Hypnotics and sedatives	Temazepam (10)	0
	Zolpidem (5)	0
	Lormetazepam (1)	22
	Temazepam (20)	40
	Zaleplon (10)	40
	Triazolam (0.25)	89
	Flunitrazepam (1)	115
	Zolpidem (10)	119
	Zolpidem (20)	214
	Zopiclone (7.5)	240
	Triazolam (0.5)	247
	Flunitrazepam (2)	461
Antipsychotics	Sulpiride (400)	0
	Haloperidol (3)	93
	Promethazine (27)	491
Antidepressants	Fluoxetine (60)	0
	Paroxetine (30)	0
	Imipramine (75)	32
	Trazodone (100)	87
	Mianserin (10)	185
	Amitriptyline (25)	327
	Amitriptyline (50)	380
Antihistamines	Fexofenadine	0
	Loratadine (10)	0
	Terfenadine (60)	0
	Diphenhydramine (25)	54
	Diphenhydramine (50)	92
Illicit drugs	d-amphetamine (24.75)	0
	d-amphetamine (4.25)	0
	THC oral admin. (8.25)	0
	THC smoking (5)	66
	THC oral admin. (13.5)	68
	THC smoking (13.5)	70
	THC oral admin. (24.5)	215

Note: For missing substance/dose combinations no degree of impairment exists.

Figure 4. Diazepam 20 mg, time-dependent impairment (29 studies, 276 effects)



In the case of narcoanalgetics, hallucinogens, and opioids used mainly in substitution treatment for opioid addicts (morphine, methadone and buprenorphine), the number of published studies was too low to carry out a meta-analysis, so their effects on drivers were summarised in a review of the literature. Finally, the project's expert workshop on heroin substitutes concluded that no distinction should be drawn between patients undergoing substitution treatment and patients receiving other medicinal treatments, but addiction to other impairing substances is clearly an exclusion criterion for driving. Patients are not fit to drive during the adjustment phase, but this is generally short (around 3 weeks). Periods of large dose changes require attention but gradual detoxification does not. The three substitution substances and the amount of the daily dosage in milligrams are no criteria for the fitness to drive, as long as they are adequate for each client. With all this in mind, decisions should be made on a case-by-case basis.

Driving tests

These were standardised, and comprised tests of road tracking ('standard deviation of the lateral position', or weaving/swerving), car following and risk-taking (overtaking, jumping traffic lights), as well as laboratory tests that included attention, cognitive and reaction tests. All studies on the impact of illicit drugs adopted placebo-controlled, double-blind, within-subjects study designs. All studies employed representative subject samples, i.e. recreational users of MDMA and dexamphetamine, and patients of the prescribed medicines being tested, who were screened for presence of alcohol and other drugs before each test. Most of the studies employed crossover designs to provide maximal statistical power with relatively small sample sizes. Most were conducted in real traffic although some utilised advanced driving simulators; one, for legal reasons, was carried out on a closed driving circuit.

None of the studies investigating the effects of stimulants on driving (MDMA and dexamphetamine) found that drug consumption alone resulted in increased impairment or risk-taking. Increased risk-taking behaviour was observed only in the case of additional alcohol consumption. In general, low doses of stimulant drugs produce neutral or even stimulating effects on a range of psychomotor functions. However, some studies found that stimulants may also have detrimental effects on specific cognitive functions and increase risk-taking behaviours. Considering the likely drug use setting, the stimulant effects of MDMA and amphetamine were not sufficient to overcome or compensate for driving impairments resulting from concomitant alcohol use or a night's sleep deprivation; in fact, MDMA in combination with alcohol (or sleep deprivation) impaired driving performance. Moreover, users of stimulant drugs were not aware of post-acute fatigue effects (the 'comedown'). One night of sleep deprivation alone caused impairments comparable to those observed under the influence of 0.8 g/l BAC.

With regard to medicines, zopiclone (7.5 mg) and alprazolam (0.5 mg) produced significant driving impairment in patients as well as in healthy control subjects, although chronic users experienced no subjective feelings of reduced alertness or drowsiness. Thus, insomniacs and anxiety patients may believe that they can drive safely while taking these drugs, even though their performance is in fact impaired. However, the driving performance of patients suffering from insomnia who had been prescribed short-acting hypnotics or low doses of hypnotics generally did not differ from that of normal sleepers. In contrast, sleep apnoea was strongly correlated with driving impairment. In the case of analgesics, it was found that the impairment potential of codeine/paracetamol combinations increases with age. Dronabinol (Marinol®), synthetic THC used for the treatment of chronic pain, impaired driving performance in occasional cannabis users to the same level as 0.5 g/l BAC, whilst the effect was less in daily cannabis users. The driving performance of patients suffering from chronic pain and undergoing long-term treatment with opioid analgesics was generally similar to that of healthy control subjects.

The details of the research and findings can be found in the deliverables from Work Package 1 — see Annex 3.

What is the risk of being seriously injured, dying or of killing someone after taking drugs and driving?

In statistical terms, the relative risk, also known as the risk ratio, signifies the risk of an event (injury or death by crashing a car) relative to exposure (consuming a psychoactive substance). The correct way of calculating risk is to follow a large cohort of drivers for some time, observe how many consume psychoactive substances and then observe how many crash. Obtaining results on a large scale in this way would be prohibitively expensive, so the practical way of calculating the risk of such a rare event is to carry out a case–control study and use the results to calculate odds ratios, which in this case approximate to relative risk. A risk ratio of 3, for example, means that a substance-positive driver is three times more likely to crash than a sober driver.

In the DRUID project, to calculate the relative risk of having a serious accident when positive for a substance, four numbers were required:

- the number of cases (here, obtained from hospital studies of drivers seriously injured/killed) positive for a given substance group;
- the number of controls (here, drivers in the roadside surveys on roads close to those hospitals) positive for a given substance group;
- the number of cases (here, obtained from hospital studies of drivers seriously injured/killed) negative for any substance; and
- the number of controls (here, drivers in the roadside surveys on roads close to those hospitals) negative for any substance.

Once these numbers had been collected, the relative risk of a driver being seriously injured in an accident was approximated to the odds ratio between the odds of a driver being seriously injured in an accident while positive for a given substance and the odds of being seriously injured while negative. The relative risk of a driver being killed in an accident was estimated in the same way. The odds ratios for the different substance groups were calculated using logistic regression and adjusted for age and gender, as an approximation for the relative risk. In both cases, samples were considered positive if the concentration was at or above the equivalent cut-off in either blood or oral fluid.

Data from the case study population consisted of samples from the hospital studies of seriously injured drivers in six countries (Belgium, Denmark, Italy, Lithuania, the Netherlands, Finland) and those of killed drivers from four countries (Portugal, Finland, Sweden, Norway). In total, 2 490 seriously injured drivers and 1 112 killed drivers were included. Data from the control population came from the roadside surveys in the same countries; in total, 15 832 drivers participated in the control sample of the seriously injured drivers and 21 917 drivers participated in the control samples of killed drivers; data were weighted for the national distribution of traffic in each of eight time periods of the week. The relative risk estimates were adjusted for age and gender.

Despite the scale of the project, the number of subjects, both cases and controls, testing positive for each substance was very low, with some countries finding none. Although this is fortunate from a road safety point of view, it results in imprecise odds ratio estimates with broad confidence intervals. There are also considerable variations among countries' results that are not easy to explain. The data were pooled to give more reliable ratios, with smaller confidence intervals, and are presented as four general levels of increased risk of being seriously injured or killed in a traffic accident. Nevertheless, the overall results for illicit drugs in particular, because of the very low number of positives (cocaine and illicit opioids) or wide variability between countries (cannabis and amphetamines), should be treated with caution. The rarity of positive toxicological results also meant that the small numbers of drivers with (very) low and (very) high substance concentrations were pooled. It was not possible to determine the difference between concentrations when calculating the risk for any substance other than alcohol. Although benzoylecgonine is an inactive metabolite of cocaine, the risk of being seriously injured or killed while positive for benzoylecgonine was calculated in order to determine if the risk of road traffic accidents is increased when only metabolites are present, i.e. after recent drug use.

Table 2. Project findings — the relative risk level of being seriously injured or killed in an accident while positive for various substance groups

Risk level	Relative risk	Substance group
Slightly increased risk	1–3	0.1 g/l ≤ alcohol in blood < 0.5 g/l Cannabis
Medium increased risk	2–10	0.5 g/l ≤ alcohol in blood < 0.8 g/l Benzoylecgonine Cocaine Illicit opioids Benzodiazepines and z-drugs Medicinal opioids
Highly increased risk	5–30	0.8 g/l ≤ alcohol in blood < 1.2 g/l Amphetamines Multiple drugs
Extremely increased risk	20–200	Alcohol in blood ≥ 1.2 g/l Alcohol in combination with drugs

Notes: Cannabis and amphetamines: owing to very different single-country estimates, the risk estimates must be treated with caution. Benzoylecgonine, cocaine and illicit opioids: owing to few positive cases and controls, the risk estimates must be treated with caution.

This elevated risk for amphetamines and other stimulants is very different from the findings of the experimental studies in the DRUID project. When amphetamine was found in drivers injured or killed in road traffic accidents, the median concentrations were very high compared with the concentrations of subjects in the experiments; these may have detrimental effects on self-perception, critical judgement and risk-taking, and while the stimulating effects are wearing off the driver may suffer fatigue, anxiety and irritability. It is also likely that drivers who choose to drive when positive for (large concentrations of) amphetamines are more prone to taking risks than the average road user. The risk associated with benzoylecgonine, which is not an active agent, might be caused by sleep deprivation after consumption of cocaine.

Using a different method, a pharmacoepidemiological study carried out in the Netherlands linked pharmacy, traffic accident and hospital databases to calculate the relative risk of a patient being involved in an accident while using medication. The case population was defined as adults involved in a traffic accident between 2000 and 2007 and who were driving and received medical assistance. The control population was defined as adults holding a driving licence who were not involved in a traffic accident during the study period. In total, 3 963 cases and 18 828 controls were selected for the case–control analysis. Calculations showed an increased accident risk for drivers exposed to at least one psychotropic medication (relative risk 1.3), drivers undergoing treatment with a combination of medicines (relative risk 1.5) and those taking modern antidepressants (relative risk 1.7). The study identified high-risk groups such as new users, intermediate and long half-life benzodiazepine users, female users and young/middle-aged users.

Responsibility studies involve deciding whether or not the driver was responsible for the accident, rather than simply being involved in it. This can be assessed in two ways. In the first, investigation

teams comprising traffic safety and car inspection engineers, without knowing of any impairment of the driver, study each accident to determine responsibility. In the second, researchers compute a responsibility score, based on information from eight groups of characteristics: road conditions; traffic conditions; vehicle conditions; crash type; complexity of the driving task; complexity of traffic regulation; tiredness of the driver; and witnesses' comments. The DRUID project used an adaptation of the 'responsibility score' calculation to estimate the risk of being responsible for a fatal accident while positive for a psychoactive substance.

Relative risk estimates for the responsibility of drivers killed while positive for alcohol and other drugs were based on data from Germany, Lithuania, Hungary and Slovakia. In total, 483 drivers were included in the study. However, largely because of the low number of controls, the analysis could not detect an effect of individual substances on the risk of being responsible for a fatal accident, except for BAC ≥ 1.2 g/l. Nevertheless, the DRUID project also benefited from the dataset of an earlier responsibility study in France, to which the new DRUID cut-offs were applied. Blood samples were taken from 7 455 car drivers involved in fatal accidents in the period October 2001 to September 2003, whether they were killed, injured or unharmed; therefore, the group was different from the killed drivers above, and so the two datasets could not be combined. The reference group was car drivers with a BAC < 0.1 g/l. Again, the relative risk estimates were approximated to odds ratios. This analysis found that the risk of being responsible for a fatal crash was five to eight times higher for a driver under the influence of alcohol (BAC ≥ 0.1 g/l) than for a sober driver; the risk of severely intoxicated drivers (BAC ≥ 1.2 g/l) being responsible for a fatal crash was 15–21 times higher than that for sober drivers. Drivers involved in fatal accidents and positive for cannabis (≥ 1 ng/ml) had a risk about twice that of drivers not positive for cannabis. Combined use of alcohol and cannabis multiplies the risk of causing a fatal accident. In the case of amphetamine, cocaine and illicit opioids, odds ratios of responsibility adjusted for age and gender were not significantly different from 1, meaning that the risk of responsibility for positive drivers was not significantly different from that of sober drivers. This may have been a result of the small number of drivers in the sample that tested positive for those substances.

The details of the research and findings can be found in the deliverables from Work Package 2 — see Annex 3.

Part B: Examining the possible responses

In addition to understanding the size of the problem, policymakers need to know how to respond to it efficiently and effectively. This is particularly complex, given the difference in legal status of the substances involved and the wide variety of social attitudes towards them. The problem can be addressed in various ways. Prevention programmes targeting illicit drugs usually consist of information campaigns and are frequently aimed at young people in an attempt to dissuade them from taking drugs and driving. However, prevention programmes aimed at users of psychoactive medicines may be broader in scope, addressing physicians and pharmacists to encourage them to review their prescribing and dispensing practices, as well as addressing patients who may be taking those medicines and are unaware of their effects on driving skills. Laws may act as a deterrent, punishing impaired driving or simply driving with any of these substances in the body, and these may be enforced by police using clinical tests or analytical roadside screening devices. Rehabilitation of offenders aims to stop reoffending in the future. All these responses require financial and human resources, which are under increasing pressure in Europe at present, so it is essential that policymakers can identify the most efficient and effective responses and avoid those that may seem instinctive or attractive but, when evaluated objectively, do not give value for money.

How to assess the driver's fitness to hold a licence?

Driver licensing across Europe is regulated by Council Directive 91/439/EEC of 29 July 1991 on driving licences. Annex III of that Directive states that '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'. Addressing legally prescribed medicines, it also states that '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.' As a Directive, the obligations of this law must be implemented in all countries in the EU; individual countries should not deviate from it. With this in mind, one of the aims of the project was to consider whether, 20 years later, the wording of the Directive is still appropriate in the light of developments in road safety and public health policy.

Little is known about how the Directive is implemented in the different countries. Therefore, a questionnaire survey of driver licensing authorities and experts was conducted in 29 European countries (all EU Member States and Norway and Switzerland) requesting information on guidelines for physicians on prescribing medicines with impact an on driving performance and on assessing fitness to drive. In addition, existing guidelines for pharmacists on advising patients while dispensing those medicines were considered. The survey found that the regulations in the different countries dealing with the procedures for assessing fitness to drive are mainly in line with the European Council Directive. However, practical implementations and the assignment of responsibilities differ from country to country. Based on these findings, it was very difficult to derive a 'best practice' for implementation. Nevertheless, the project made a number of recommendations to be considered when redrafting the Directive, including clearer distinction between (illicit) drugs

and medicines and updating terms such as 'abuse', 'dependence' and 'regular use', which now have changed or unclear meanings. Importantly for users of psychoactive medicines, it recommended that the final decision on fitness to drive should take into account not only the substance involved but also the underlying reason for taking medicines and comorbidity factors.

The details of the research and findings can be found in the deliverables from Work Package 7 — see Annex 3.

Which public information campaigns are effective?

A review of existing information campaigns on the risks of driving after taking drugs or medicines found a total of 75 information campaigns from 13 different countries, including the United States, Canada and Australia. The majority of those (37) concerned driving under the influence of drugs, while 22 gave information about medicines alone, and 16 addressed both illicit drugs and medicines. Thirty were designed specifically for young people, 23 for the general public, 16 for physicians and/or pharmacists, nine for teachers, seven for patients using particular medicines, four for parents and five for another target population (e.g. drug users, heavy vehicle operators, employers). Some campaigns were designed for more than one target population. Most of the information campaigns identified were conducted through the mass media. Brochures (3–19 pages) were the medium used most frequently, followed by posters, print press, websites, booklets, television and radio commercials, leaflets, tutorials and other media. Most campaigns were run by governmental organisations or road safety organisations.

Information on the impact of the campaign was found for only 7 of the 75 campaigns, and all these evaluations documented a positive outcome. However, some simply measured the impact in the form of awareness of the campaign (minimum effect), rather than the impact on driver attitude and behaviour (maximum effect). The effects were mostly assessed through interviews; only one campaign gathered objective data concerning drug-related road deaths. As only a few evaluations were found, and these campaigns and their evaluations were performed in different ways, it is not possible to draw conclusions concerning the association between the design of the campaigns and their effectiveness. Therefore, the project was unable to make any recommendations as to the design of an effective information campaign. Nevertheless, the study noted the conclusions of broader research on similar themes, such as the EU's GADGET project, in which a large international sample of evaluated campaigns was collected, and the effect of the campaigns on accidents was evaluated as a function of certain variables ([10]). Future campaigns concerning driving under the influence of drugs and/or medicines should follow a common evaluation, in order to develop more effective campaigns. Detailed guidance for evaluating road safety campaigns has been drawn up by the EU's CAST project ([11]).

The details of the research and findings can be found in the deliverables from Work Package 7 — see Annex 3.

([10]) http://www.kfv.at/index.php?id=829&contUid=2141
([11]) http://www.cast-eu.org/

How could psychoactive medicines be better classified, labelled and dispensed?

The DRUID project reviewed existing national systems that classified medicines in terms of their effect on driving performance. In total, 16 systems were found, with varying numbers and descriptions of categories. A classification and labelling system was developed (Table 3) that classified medicines into four categories. The first step in harmonisation across Europe was achieved with the adoption of the Guidelines for the Summary of Product Characteristics in September 2009 (valid from May 2010), which specify four categories — (a) no or negligible influence; (b) minor influence; (c) moderate influence; and (d) major influence on driving fitness — with some important guidance in special circumstances.

Table 3. DRUID categorisation system for medicines and driving

Information for physicians and pharmacists		**Warning for patients** (with warning symbols and standard descriptions per country)
Description of categories with levels of impairment (1)	**Information on how to advise patients**	
Category 0 Presumed to be safe or unlikely to have 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 have minor adverse effects on fitness to drive	Inform the patient that impairing side-effects may occur, especially during the first days that may have a negative influence on his or her driving ability. Advise the patient 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 have a moderate adverse effect on fitness to drive	Inform the patient about the possible impairing side-effects and the negative influence on his or 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 to the patient	**Warning level 2** Do not drive without the advice of a healthcare professional. Read the relevant sections on driving impairment in the package insert before consulting the physician or pharmacist
Category 3 Likely to have a severe adverse effect 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 or her driving ability. Urgently advise the patient not to drive. Consider prescribing a safer medicine, if acceptable to the patient	**Warning level 3** Do not drive. After a period of treatment, seek medical advice about the conditions to start driving again

Note: (1) The assigned categories relate to the acute or first-time use of the medicine (at the start of treatment).

Based on this, 1 541 medicines available on the EU market were categorised. The distribution within the categories was as follows: category 0, 50.3 %; category 1, 26 %; category 2, 11.2 %; category 3, 5.8 %; multiple categories, 4.4 %; and 'depending on the medicine in combination', 2.3 %. Thus, about 17 % of medicines on the EU market had a relevant influence on driving skills.

It is not easy to adapt all the different current national approaches to this new categorisation system. Nevertheless, discussions with the Pharmacovigilance Working Party (PWP) of the Committee for Medicinal Products for Human Use have led to a consensus on developing a basic two-level framework for warnings in the patient information leaflet in the package, both for medicines without a potential relevant influence on driving (no, negligible or minor influence) and for medicines with a potential relevant influence on driving (moderate or major influence). At the time of writing (December 2012), the responsible Commission services had not yet endorsed this agreement and so the PWP had not received the mandate to implement it.

It is normal for information on the side-effects of medicines, such as effects on driving ability, to be included in the patient information leaflet inside the package. However, some European countries now include a pictogram on the medicine package itself that conveys the risks when driving. To understand the effectiveness of these, a total of 1 006 patients visiting pharmacies in Spain and the Netherlands were asked their opinions on two pictograms that distinguished between different levels of impairment, one with warning triangles, used in France (Figure 5), and another with ratings developed by the DRUID project (Figure 6).

Figure 5. Triangle model pictogram (France)

Figure 6. Rating model pictogram (DRUID)

The studies showed that both pictograms were effective in communicating risk. A large majority of patients (70–80 %) considered these pictograms clear and self-explanatory, with a preference for the DRUID rating model. Furthermore, 78 % of the patients stated that they would drive less frequently or not at all (depending on the medicine category) if confronted with the pictogram on the medicine box.

The DRUID project also reviewed national guidelines for prescribing and dispensing medicines that might affect driving performance to see how they varied across Europe. It aimed to examine how qualified personnel such as physicians and pharmacists could or should play a role in helping patients understand the risks of driving while taking psychoactive medications. The project found that the guidelines are typically recommendations, rather than strict and binding regulations, and that the role, responsibilities and tasks of physicians and pharmacists are not defined uniformly. Nevertheless, a common recommendation is that physicians and pharmacists should give their patients the most appropriate advice on medicines and their effect on driving performance and should assist the patient with the decision whether or not to drive while using medicines. However, studies of physicians and pharmacists in Belgium, Spain and the Netherlands showed that over two-thirds received no education regarding the effects of medicines on driving during their academic studies or professional postgraduate education.

To address this, the DRUID project developed a software package that could be integrated into the software used in the physicians' and pharmacists' daily practice to implement DRUID prescribing and dispensing guidelines. After 6 months of using this, there was a positive change in knowledge and behaviour in both professional groups, although it was more pronounced among pharmacists, perhaps as they are more used to instructing patients on the side-effects of medicines. This shows that such decision support tools are welcome and usable and can improve the quality of healthcare.

The details of the research and findings can be found in the deliverables from Work Packages 4 and 7 — see Annex 3.

What limits should policymakers set for psychoactive substances in drivers?

The project aimed to develop recommendations concerning legal measures to combat drink- and drug-driving. To do this, an extensive literature study was carried out, focusing both on theories of sanctioning and also on empirical research results on drink- and drug-driving sanctioning (e.g. general deterrents such as policies and changes in the law and specific deterrents such as jail sanctions and fines). A questionnaire to gather information on legal regulations regarding drug-driving and legally imposed cut-off limits for illicit psychoactive substances was distributed in the European Member States, Croatia, Norway and Switzerland, complemented by official data from the EMCDDA. Finally, DRUID experts in the fields of experimental studies, epidemiology and toxicology collaborated closely to give recommendations on how to determine legal cut-off limits. For this, the experts had to consider issues such as the data behind estimations of accident risk, the pros and cons of different research methods, the criteria to define cut-off limits, the different

substances and their prevalence, metabolites, combined consumption, medicinal use, and the different analytes and bodily fluids (whole blood, plasma, oral fluid, dried blood spots) and conversion factors between them.

There are three groups of options available to policymakers when setting limits: setting legal limits, zero tolerance and impairment. Those setting legal limits, often known as 'per se laws', establish a fixed substance limit (e.g. BAC): any driver in whom the concentration of a particular substance reaches or exceeds the legal limit is considered to have broken the law without there being a need to demonstrate any further signs of impairment. Zero tolerance laws are a specific subgroup of laws setting legal limits with a substance concentration of zero. This means that any detectable amount of relevant psychoactive substances in the driver's body fluids has to be considered as a violation of the law. In the case of impairment legislation, it must be proven in each case that the driving skills of the driver were adversely affected. Signs of impairment will usually be observed during the police stopping procedure, during which most European countries use fixed testing protocols. These options were considered for the three groups of psychoactive substances: alcohol, medicines and illicit drugs.

Laws setting legal limits are the most effective approach to combat drink-driving. The standard legal limit should not be higher than a BAC of 0.5 g/l, as recommended by the EU to all Member States (Commission Recommendation 2001/115/EC of 17 January 2001). The effectiveness of legal limit BAC values below 0.5 g/l is very much dependent on the prevailing societal, legal and political environment and the enforcement activity of the police in that Member State. The enactment of lower legal BAC limits for some risk groups (e.g. professional drivers, drivers of large vehicles or drivers of vehicles carrying dangerous goods) should be considered with respect to the specialities of these driver groups; the above Commission Recommendation proposed a maximum BAC threshold of 0.2 g/l. A zero tolerance approach seems to be effective for young and novice drivers. Mixed intoxication through alcohol and other psychoactive substances (including medicines) is a much greater threat to road safety than the sole consumption of these substances. Consequently, the legal BAC limit in those cases must be lower than that for the consumption of a single substance.

With regard to medicines, the project concluded that it is not reasonable to define cut-off values for patients undergoing long-term treatment. Even high doses may lead to few effects. There is no clear inter-individual correlation of dosage with impairment. Legal measures should be taken only after a traffic incident and sanctions should be triggered by impairment; such a policy may also address the recreational use of medicines. No distinction should be drawn between patients undergoing substitution treatment and patients receiving other medicinal treatments — fitness to drive should be assessed individually in each patient — but addiction to other impairing substances is clearly an exclusion criterion for driving. Alcohol increases impairment and interacts adversely with many medicines. Hence, drinking, medicine consumption and driving should be separated, and that advice should be part of the physician's consultation.

Establishing limits for driving after taking illicit drugs is more complex than establishing limits for alcohol or medicines. At present, 11 countries in Europe use the impairment approach, eight use zero tolerance or legal limits and nine combine these two approaches into a two-tier system. The zero tolerance or legal limit approach appears to be more promising, particularly as, until now, the

effectiveness of enforced impairment laws has been relatively low. Police officers should be able to detect all signs of impairment during roadside checks in order to register them in official protocols, which form the basis for a court conviction, and to be able to do this police officers will need regular special training.

To date, all countries that have legal limits use analytical cut-off limits, i.e. the lower concentrations that can be reliably identified by forensic laboratories. In some countries these are the lowest limits of quantification of the forensic laboratories; in others they have been established by experts. Some countries take into account the effects of the substances, for example by measuring only the active component of cannabis, THC, instead of the inactive metabolite. There are three classes of substance thresholds that may be used to determine cut-offs:

1. 'risk thresholds': concentrations in blood that indicate a certain risk of accident or impaired driving;
2. 'lower effect limits': the lowest concentration at which an effect on driving is observed, thus proving that there is a negative impact on driving;
3. 'limit of detection': based on technical limitations in order to guarantee a valid and reliable analytical result, although this does not necessarily indicate recent consumption of the psychoactive substance or being under the influence of it.

One of the problems of using lower effect or risk threshold limits for illicit drugs is effectively establishing the dose that can be taken while still remaining under the limit. The establishment of lower effect limits does not mean that the use of illicit drugs when driving is accepted. In some countries (e.g. Finland and Sweden), the presence of drugs below the limit set for driving will lead to prosecution for drug use. Another problem is that, in determining 'lower effect limits' for stimulant drugs such as amphetamines and cocaine, the correlation between drug concentration and the risk of traffic accidents/impairment is variable or insufficiently documented. Inactive metabolites may also need to be included in the legislation when the parent drug is unstable and is metabolised very rapidly; for example, cocaine. If a country decides to include inactive metabolites such as benzoylecgonine, the cut-off should be so high that cocaine consumption a long time ago (e.g. 12 hours, as the time for post-acute effects) can be excluded.

It is not realistic to develop cut-off limits for all existing medicines and illicit drugs. The proliferation of new psychoactive substances complicates the matter further. The legal limit law, listing a few substances, may be combined with an impairment law, in which all other impairing substances are covered. In this scenario, there is a quick and simple procedure for the most common drugs and a more elaborate one for the less frequent cases, including medicines and combinations of drugs. For drug combinations, some experts recommend using limits of quantification rather than legal limits set at the lower effect. However, to gain the compliance of the population, clear legislation, which differentiates drug and traffic policy, will need to be implemented.

To determine risk thresholds for the most common illicit drugs, the DRUID partners set out to find, for each substance, the concentration in blood at which the accident risk is equivalent to the risk associated with 0.5 g/l BAC, this being the limit at which alcohol-impaired driving is tolerated in most European countries. This implies that a certain level of risk is acceptable, and so a similar

approach could also be used to define threshold quantities of illicit drugs in the blood. However, in the epidemiological studies the number of drug-impaired drivers was so small that it was possible to calculate risk thresholds only from the meta-analysis. In the case of THC, the epidemiological, experimental and meta-analytical approaches resulted in rather low risk estimations, so THC seems to be much less impairing and risky than most of the other substances examined. In the meta-analysis a serum concentration of 3.8 ng/ml THC (≈ 2 ng/ml in whole blood) was shown to be as impairing as 0.5 g/l alcohol. This value could be an empirical basis for a threshold discussion, but such a discussion should address the question of whether determining risk thresholds as equivalents to 0.5 g/l BAC is politically feasible, partly because a BAC of 0.5 g/l is not a legal limit in all European countries. Some Member States have lower alcohol limits and some are currently discussing a zero tolerance approach, and therefore risk threshold calculations for THC would have to be adapted accordingly.

The details of the research and findings can be found in the deliverables from Work Package 1 — see Annex 3.

How well do roadside detection systems work?

In the early 2000s, the EU research projects Rosita and Rosita-2 established standards for on-site screening devices for drugs and investigated whether the testing devices at that time, screening oral fluid or urine, could achieve a standard of accuracy such that they could be used by traffic police with confidence. The results showed that those devices required more development. Five years later, the DRUID project once again evaluated on-site screening devices (all of which screened oral fluid, which provides better information on recent drug use), in both practical and analytical terms. Bearing in mind the time and money that the use of such devices requires, the project also evaluated clinical signs of impairment, such as bloodshot eyes, uncoordinated movements and aggressive behaviour, to see if these could be used to accurately pre-screen drivers before use of the oral fluid screening devices.

The practical test of the devices considered aspects such as the time taken to collect a sufficient oral fluid sample, the time taken to analyse the sample, hygiene aspects and the officers' impressions of the reliability and simplicity of the test. Thirteen roadside testing devices were used in six countries by trained police officers in 2 960 roadside tests. As a result, eight devices were evaluated as 'promising' for roadside use by police officers, and these were then submitted for analytical evaluation.

The analytical evaluation was carried out in Belgium, the Netherlands and Finland from October 2007 to December 2009. Tested substance classes were amphetamine(s), methamphetamine, MDMA, cannabis, cocaine, illicit opioids and benzodiazepines. Study populations consisted of randomly selected drivers from the DRUID roadside surveys, drivers suspected of driving under the influence of drugs, patients in drug treatment centres and rehabilitation clinics, and customers of coffee shops.

At the same time, a checklist for clinical signs of impairment was evaluated in order to determine if visible signs of impairment can be used as preceding selection criteria for performing an on-site

test. The checklist comprised 24 different symptoms, based on several existing checklists, e.g. one developed for the German police and previously used in the European IMMORTAL (Impaired Motorists, Methods of Roadside Testing and Assessment for Licensing) project.

How do you test a test? Sensitivity, specificity and accuracy

To find whether a test is correctly able to identify those people who are positive and those who are negative, statisticians use the terms 'sensitivity', 'specificity' and 'accuracy'. Sensitivity refers to the proportion of positive people who are correctly identified as positive. Specificity refers to the proportion of negative people who are correctly identified as negative. The two are combined to calculate the accuracy. Specificity of 100 % would mean that no driver who has refrained from taking drugs would be accused of drug taking ('false-positive'), while 100 % sensitivity would mean that no driver who has recently taken drugs would be declared clean (a 'false-negative').

The results of the evaluations of the checklist for clinical signs of impairment were not very promising. The indicators proved to be effective mainly in cases of high concentrations or very recent use. The pupil reaction test was the best predicting parameter, especially for amphetamines and THC. The checklist scored a low sensitivity value (Dutch study) and an even lower correlation of symptoms with actual presence of drugs (Belgian study) and in some cases there were difficulties in correlating the symptoms with actual drug use owing to insufficient data collection (Finnish study). More experience, better training and selecting times and locations with a high incidence of drug-driving may improve the effectiveness of such checklists.

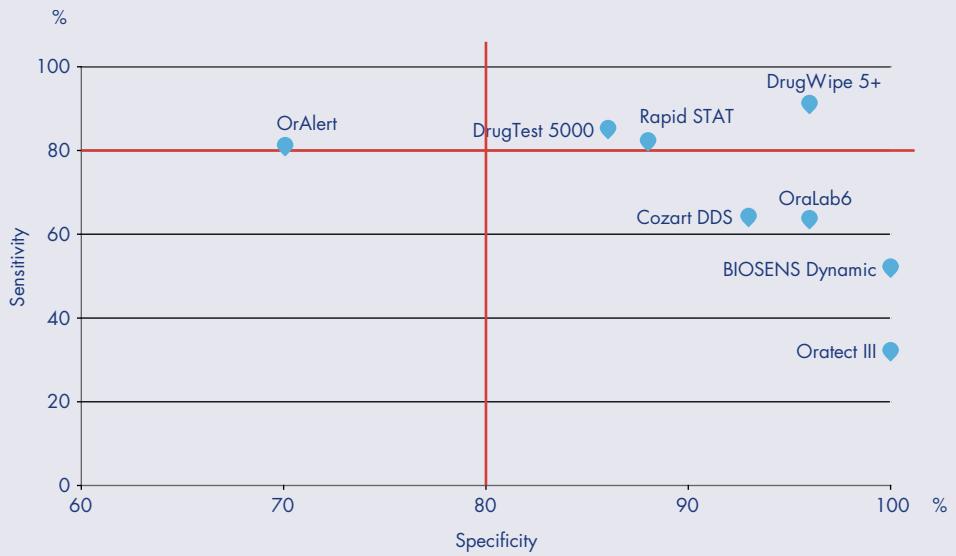
The performance of the eight promising oral fluid screening devices was assessed, based on sensitivity, specificity, accuracy, positive predictive value and negative predictive value, for the individual substance tests of the device. These were assessed based on both DRUID and manufacturer cut-off limits. Sensitivity, specificity and accuracy performance values of 80 % or more were set as a desirable target value. In order to obtain statistically valid calculations, it was determined that at least six positive (in the case of sensitivity) or six negative (in the case of specificity) cases were needed.

The results were as follows:

Drug group	Sensitivity range (%)	Specificity range (%)	Accuracy range (%)
Amphetamine	0–87	91–100	84–98
Cannabis	11–59	90–100	41–82
Cocaine	13–50	99–100	86–100
Opioids	69–90	81–100	75–99
Benzodiazepines	48–67	94–100	77–100

None of the tests reached the target value of 80 % for sensitivity, specificity and accuracy for all the separate tests they comprised. Not enough positive cases were gathered to successfully evaluate any of the methamphetamine, MDMA or phencyclidine (PCP) tests for the devices in which these were included. In comparison with the devices tested in the project Rosita-2 in 2003–05,

Figure 7. Sensitivity and specificity of the oral fluid screening devices for any positive result



minor developments can be seen in test precision for amphetamines, opioids and benzodiazepines, but no significant improvements can be seen for cannabis and cocaine. Nonetheless, in general, devices can be expected to improve in performance as the field develops.

In addition to evaluating the individual substance group tests, an overall evaluation was performed as a measure of the usefulness of the devices in police checks to identify drug drivers generally, even if they could not correctly identify which drug was actually present. In this case, any positive drug screening result was viewed as valid, providing that the confirmation sample contained one of the DRUID substances analysed. For example, if a test kit declared a positive finding for amphetamine, but the confirmation sample tested positive only for cannabis, it would be recorded as a valid result. In this overall evaluation, three of the devices performed at > 80 % for sensitivity, specificity and accuracy (Figure 7).

When assessing the evaluation results above, the prevalence of drugs in the populations studied should be considered; higher prevalence can lead to enhanced sensitivity, whereas lower prevalence can lead to enhanced specificity and higher accuracy. If the suitability of the device is considered based on the above results, the type and prevalence of drugs within the population for which the device is intended to be used should be taken into account; for example, the overall evaluation performance of the DrugWipe 5+ can be largely attributed to its strong individual performance in the amphetamines test and the prevalence of these substances in the Nordic study population.

Collecting evidence: dried blood spot analysis

Once a driver has screened positive, collecting blood for evidence can be complicated. Whole blood and plasma samples should be taken only by medical personnel, and this can be difficult in

drivers with limited venous access, such as injecting drug users. Intoxicated drivers are not always calm. Blood should be transported and stored in special low-temperature conditions to stop the samples degrading and to avoid the risk of infection. The DRUID project took advantage of a unique opportunity to test the possibility of an alternative option for determining the presence of analytes in blood.

For years, dried blood spot (DBS) analysis has been routinely used for screening newborn infants for congenital metabolic disorders. Analysis of DBS specimens for drugs has become feasible with the advent of increasingly sensitive mass spectrometry techniques, and is now a valuable tool in therapeutic drug monitoring. DBS is a less invasive alternative to taking a blood sample; it can be prepared using capillary blood after a finger or heel prick by non-medical personnel. A spot of whole blood is dried onto a custom-made card, which is then folded and left to dry at room/ambient temperature for 3 hours. Roadside sampling should reflect the actual blood concentration, and hence driver impairment, at the time of being stopped by the police or at the scene. DBS samples can be transported and stored in sealed envelopes with desiccant packs and can be sent by regular mail.

The project examined the feasibility and accuracy of detecting the most common substances used by drivers using DBS analysis compared with analysis of whole blood samples. In fact, by using liquid chromatography–mass spectrometry, all investigated analytes could be determined with sufficient lower limits of quantification. The evaluation data showed no significant differences in precision: all substances investigated in the presented studies could be determined in a DBS as reliably as in a whole blood specimen. Thus, the project demonstrated that DBS drug analysis can be regarded as a valuable and inexpensive alternative to the determination of substances in whole blood. Such use of DBS could greatly facilitate blood analysis in drug-driving cases in the near future.

The details of the research and findings can be found in the deliverables from Work Package 3 (DBS in Work Package 1) — see Annex 3.

What are the costs and benefits of investing in drug-driving enforcement?

As it is known that some drivers are under the influence of drugs, and some of these greatly increase the risk of serious injury or death in accidents, the logical reaction is to demand an increase in enforcement and detection. The policy goal of increased enforcement, targeting driving under the influence of psychoactive substances, would be to increase the benefits to society (reduce societal costs) through a deterrence effect that should reduce driving under the influence of psychoactive substances, and subsequently reduce the toll of fatalities and injuries. However, there are also costs involved in an increased level of enforcement, such as the costs of screening and control equipment and police time, as well as additional medical and judicial costs in the case of suspicions and convictions. These would also vary according to the device used. Therefore, as part of the DRUID project a cost–benefit analysis (CBA) was carried out, assessing to what degree increased enforcement against driving under the influence of drugs would be profitable in economic terms for society, together with an assessment of which of the existing devices for such enforcement would be the most profitable to use.

A benefit–cost ratio was estimated according to the formula:

$$\text{Benefit–cost ratio} = \frac{\text{Present value of all safety benefits}}{\text{Present value of implementation costs and time used}}$$

In addition to the CBA and estimates of net benefits and the benefit–cost ratios of increased traffic police enforcement, the study also included a cost-effectiveness analysis.

The CBA aimed to answer two questions:

1. To what degree is the enforcement of legislation against driving under the influence of drugs profitable in economic terms for society?
2. Which of the existing devices for such enforcement is the most profitable to use?

The basic idea of the CBA model is that a particular scenario or group of scenarios is compared with the reference situation or baseline, which is a continuation of the current situation. Thus, CBA compares economic benefits and costs arising from the implementation of specific policies/projects with a 'do-nothing' reference/baseline. The model was completed with data from three countries (Belgium, the Netherlands and Finland).

DRUID considered three scenarios in CBA: a small (50 %), medium (300 %) and large (1 000 %) increase in the enforcement of drug/medicine oral fluid testing, while maintaining the current level of alcohol enforcement. As the CBA was applied to different countries, with different prevalence of the different drugs/medicines (and alcohol), the effect of the prevalence was also taken into account. The prevention of deaths and serious injury brought about by increased enforcement is balanced against the time-consuming process of on-site oral fluid screening, the rather high cost of the devices and the relatively low sensitivity for cannabis (the most common illicit drug), which would imply a high number of potentially dangerous false-negatives. One further element in the scenarios was to recalculate the 300 % drug enforcement increase together with a 10 % reduction in alcohol enforcement. This aimed to simulate an adjustment of random alcohol breath testing to maintain current overall enforcement levels/resource use, i.e. to transfer a share of alcohol enforcement to drug enforcement. In this way the project could compare the effects of an increase in resources with a redistribution of resources.

The calculation differentiated between road users, who would benefit from safety improvements (due to enforcement) but lose time when being tested (negative benefits), and the public sector, which would cover the costs of the enforcement efforts, prosecution, etc., by the police, the courts and ministries.

The calculations were based on the following data:

- the effects of enforcement, i.e. the reduction in accidents, fatalities, injuries and material damage resulting from this kind of enforcement;
- the costs of (or positive benefits of preventing) accidents, fatalities, injuries and material damage;
- the costs (negative benefits) of road users' time;
- the costs of devices/equipment;

- the costs of police time;
- the costs of laboratory analyses;
- the costs of the judicial system.

The basic requirement for increased drug enforcement to be considered efficient is a benefit–cost ratio of 1.5 or higher, while a benefit–cost ratio of between 0 and 1 indicates that the cost of increased enforcement is higher than the benefit. The benefit–cost ratios were calculated as follows:

Enforcement increase	Belgium	Netherlands	Finland
50 %	8.04	19.60	1.27
300 %	5.09	13.74	0.79
1000 %	1.82	5.04	0.28

The analysis of scenarios in the three countries shows that increased drug control would be most profitable for the Netherlands and least profitable for Finland. This is logical in terms of the baseline enforcement level, as in Finland the level of drug enforcement (tests per 100 000 inhabitants) is already 25 times higher than that in the Netherlands. In the Netherlands an even larger increase might be cost-efficient.

This finding was supported by a simulation of the three countries increasing their level of enforcement to arrive at a comparable enforcement level ('control density'):

Country	Enforcement increase	New drug control density	Benefit–cost ratio
Belgium	300 %	0.108 %	5.09
Netherlands	2 000 %	0.121 %	2.70
Finland	10 %	0.160 %	1.23

However, this conclusion became more nuanced when comparing the net benefits for a 300 % increase in drug enforcement with extra resources (i.e. maintaining '100 % alcohol' enforcement) with those for a 300 % increase in drug enforcement funded by a transfer of existing resources from alcohol to drug enforcement (i.e. a reduction to '90 % alcohol' enforcement):

	Belgium		Netherlands		Finland	
	90 % alcohol	100 % alcohol	90 % alcohol	100 % alcohol	90 % alcohol	100 % alcohol
Road users net benefits (EUR)	15 162 061	23 700 208	–327 813	9 975 499	1 052 860	3 557 730
Public sector net benefits (EUR)	8 215 102	6 833 944	11 164 565	3 722 058	5 288 350	–1 796 535
Total net benefits (EUR) [1]	20 075 601	27 232 590	10 359 936	13 220 740	3 244 818	–1 335 197
Benefit–cost ratio		5.09		13.74		0.79

Note: [1] Total also takes into account fines paid by offenders, not included in this table.

In these simulations, maintaining alcohol enforcement while increasing drug enforcement led to an improved benefit–cost ratio in those countries with lower enforcement levels. While the benefit–cost ratio for the increase in drug enforcement funded from alcohol enforcement is not comparable to the case when maintaining alcohol enforcement, the net benefits can be compared. For the alcohol enforcement reduction case ('90 % alcohol'), the denominator is then normally rendered negative because of an overall enforcement cost reduction, and then the benefit–cost ratio ceases to be a robust indicator of cost efficiency. However, estimated net benefits are robust to any changes in benefits and costs, and thus can be compared between '90 % alcohol' and '100 % alcohol' cases. The net benefits calculated overall are still financially positive when funding increased drug enforcement with 10 % reduction in alcohol enforcement, even if in the Netherlands and Belgium they are lower than net benefits when maintaining alcohol enforcement. However, when the shares of the benefits distributed between road users and the public sector are closely examined, one can see that the overall increase in benefits comes at the cost of net benefits to the road user, i.e. at the cost of safety on the roads.

The final conclusion is that increased drug-driving enforcement based on roadside oral fluid screening is potentially cost-beneficial. However, this is by no means straightforward, and depends on the initial levels of both drug prevalence and law enforcement. If prevalence in traffic is low, there are fewer lives to be saved by testing. Regarding enforcement, these models show that the higher the enforcement level is to begin with, the lower the overall net benefits to society from any increase, and they may even decrease. The shares of those benefits within society should also be considered. Road user net benefits will certainly increase if the level of law enforcement for alcohol is maintained while law enforcement for drugs increases; in contrast, reducing law enforcement on alcohol to fund drug enforcement may actually have a negative impact on road safety. Therefore, to answer the two questions posed by the CBA, the first priority of enforcement should always be alcohol; other drugs take second place. The characteristics of the problem on a national level (e.g. the prevalence levels of different drugs) will determine the focus of, and devices used in, drug enforcement; devices that perform above average will contribute to a higher benefit–cost ratio than those that perform below average.

The details of the research and findings can be found in the deliverables from Work Package 3 — see Annex 3.

How effective is withdrawal of the driving licence?

Withdrawal of the driving licence refers to the removal of permission to drive. Generally, this may take one of two forms. In the first, the licence is withdrawn for a fixed period and automatically reverts to the driver at the end of that period. In the other, the driver has to pass some form of test before regaining the licence. The terms 'driving ban' and 'licence withdrawal' may be used, but these do not have a common interpretation across Europe.

Licence withdrawal is a sanction that is both a form of general deterrent and a form of special deterrent. A general deterrent aims to discourage others from committing the same crime as the offender was punished for, or a similar one, through the fear of punishment. Here, it is referred to as distinct from general prevention, which aims to strengthen public approval of the law and its

enforcement ([12]). A special deterrent aims to bring about a change in the behaviour of the accused and convicted person through the impact of the sentence. This is distinct from special prevention, which aims to rehabilitate the offender through a change in behaviour as a result of a change in attitude, and not only through the fear of penalties.

To understand the current conditions regarding licence withdrawal in the EU, all 27 Member States and three non-EU countries were sent a special DRUID questionnaire about existing legal regulations and sanctioning practices. In most countries (24/30), driving while above the legal limit of alcohol leads to withdrawal of the driving licence. Two-thirds of the countries (19/30) have a withdrawal sanction for driving under the influence of both alcohol and drugs. Twelve of the 30 countries have withdrawal sanctions for all three groups of psychoactive substances, i.e. alcohol, drugs and medicines.

Considering the different periods involved, about two-thirds of the countries withdraw the licence for a temporary period. In 10 countries, conditional withdrawal is possible, for example the withdrawal is effective at weekends or outside a certain geographical area (beyond the place of work/school/doctor's practice). Eight countries have the legal potential to reduce the withdrawal period after the driving licence has been withdrawn, for example after participation in a treatment, rehabilitation or ignition interlock programme. The withdrawal period can also be reduced for some other reasons, such as personal, professional or social circumstances, the character of the applying offender, his or her conduct after conviction or the nature of the offence.

For alcohol, there are sizable differences in withdrawal periods among the European countries. These depend on BAC limits, which vary considerably across Europe. In some countries, accidents occurring when the driver is under the influence of alcohol, as well as recidivism, i.e. another drink-driving offence within a certain time period, will lead to an extension of the withdrawal period. However, for drugs, only 22 out of 30 countries provided information to the DRUID researchers on withdrawal periods. In eight countries, licences could be withdrawn for drug-driving for periods up to 6 months; four countries indicated withdrawal periods between 6 and 12 months; five countries indicated periods between 12 and 24 months; and five countries indicated periods of longer than 24 months.

As a second step, to understand the implementation and effectiveness of these regulations and practices, findings from about 60 empirical primary studies and non-empirical studies on the general and special deterrent/preventive impact of withdrawal were analysed. Country expert workshops were carried out with experts from ministries of justice, the courts and administrative authorities, ministries of health, the rehabilitation system, the police and ministries of the interior, and ministries of transport. International expert workshops focused on licence withdrawal for specific problem groups, namely drivers undergoing substitution treatment and long-term medication treatment.

The analysis of the empirical literature revealed that the general deterrent approach includes three main factors that often overlap:

- the certainty of the punishment (including the risk of detection and the probability of the case being dropped before conclusion);

([12]) General prevention is closely related to the EMCDDA's concept of environmental prevention.

- the severity of the punishment (including the legal threat of sanctions and how they are imposed — by judicial or administrative practice);
- the celerity, or swiftness, of the punishment (how quickly after the offence is committed the punishment is applied).

The main general deterrent factor is the perceived risk of detection — not the real risk. In most cases, the perceived risk is higher than the real risk, and it is primarily influenced by the intensity of the media coverage of police enforcement operations. Laws without any discretion for the authorities are major factors in increasing the probability of sanctioning at the end of the process. However, this element must be accompanied by a high level of (real) risk of detection to achieve significant levels of general deterrence. Empirical primary findings indicate that increasing the certainty of sanctioning is much more effective than increasing the severity of sanctioning. The celerity of punishment is — besides the certainty of punishment — a further important deterrent factor.

From this, the project concluded that the certainty and celerity of sanctioning are crucial for both the general and the special deterrent impact of sanctions — above all the immediate withdrawal/suspension of the driving licence and a high level of perceived risk of detection. Driving licence withdrawal has been shown to be a greater deterrent than other sanctions (e.g. imprisonment or fines). Social disapproval, especially from peers and friends and particularly with adolescent offenders, seems to have a much greater impact than formal legal consequences. Nevertheless, the effectiveness of the severity of sanctioning is limited. The duration of withdrawal should be set between 3 and 12 months; shorter or longer periods do not seem to have a deterrent impact, and a longer withdrawal period generally leads to an increase in non-compliance and thus offenders driving without a licence as they try to manage their daily lives. Combining withdrawal with rehabilitation/treatment appears to be a more effective deterrent than the sole imposition of either measure. Conditional withdrawal, supporting a reintegration process, can be applied together with rehabilitation/treatment measures and also with regular medical checks and/or installation of an alcohol ignition interlock, which allows the vehicle to start only when no alcohol is detected.

It was not possible to make a final recommendation on either an administrative or a criminal procedure. The advantages of an administrative procedure are the celerity and certainty of sanctioning (especially in the case of legislation setting legal limits); the disadvantages of a criminal procedure are related to the considerable differences in the severity of the imposed sanctions.

Recommendations for specific problem groups included the following:

- For drivers found under the influence of alcohol, 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. An alcohol ignition interlock could be offered as an option in exchange for a reduced length of licence suspension and should be offered in combination with at least strict medical counselling or even psychological support.
- For drivers found under the influence of drugs, the general deterrent principles for alcohol are also valid.

- For patients undergoing 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 an assessment of fitness to drive, is to be recommended. For patients in substitution treatment, each will need to be assessed individually regarding fitness to drive. It is recommended that a conditional licence, based on the assessment of fitness to drive, is combined with follow-up controls — above all focusing on abstinence from the parallel consumption of other drugs.

The details of the research and findings can be found in the deliverables from Work Package 6 — see Annex 3.

How effective are driver rehabilitation schemes?

The aim of a rehabilitation scheme is to allow the driver to return to the road while minimising the likelihood of reoffending. The DRUID project included comprehensive reviews of international literature on the topics of identifying different types of drink- and drug-driving offenders, existing assessment procedures and rehabilitation measures, and the options for addicted/dependent offenders. Many organisations that provide driver rehabilitation services in the different countries contributed to investigate the measures currently implemented in Europe.

In Europe, drink- and drug-driving assessment is primarily carried out in the frame of the decision on fitness to drive. It is mostly a multidisciplinary approach, covering medical, psychological and social aspects. Objective parameters such as BAC or prior offences can serve as criteria for deeper assessments or even directly for specific driver rehabilitation. There is no uniformity across Europe regarding the implementation of drink- and drug-driving rehabilitation. Five selected European countries (Austria, Belgium, Germany, France and Hungary) served as examples for current approaches; national regulations are established for different aspects of drink- and drug-driving rehabilitation. Regarding access to such rehabilitation programmes, the survey showed that European countries use very different approaches, ranging from voluntary, through recommended, up to obligatory participation.

At least 47 providers, mainly non-governmental, private organisations in 12 European countries (Austria, Belgium, Germany, France, Italy, Hungary, the Netherlands, Poland, Portugal, Sweden, Switzerland and the United Kingdom) carry out driver rehabilitation services on a regular basis. In total, 87 driver rehabilitation programmes were found, comprising 53 for drink-driving offenders, 21 for drug-driving offenders and 13 for mixed groups (drink-driving/drug-driving/other traffic offenders). All the above-mentioned countries offer programmes for drink-driving offenders, and four of them (Austria, Belgium, Germany and Portugal) also offer programmes for drug-driving offenders. The vast majority of driver rehabilitation providers do not offer treatment programmes for substance-dependent offenders.

The literature review identified 61 studies on the effectiveness of rehabilitation programmes of drink- and drug-driving offenders. Group intervention programmes were developed and optimised for drink-driving offenders. Driver rehabilitation programmes for drink-driving offenders are based on a rather long-term tradition in development and practical application in Europe. The 'European standard

group intervention' can be described as follows: a course with 6–12 participants, using a psychological therapeutic approach with educational elements, led by a qualified course leader, often a psychologist. The programme lasts several weeks and has the same course leader and participants. An analysis of 36 studies and two reviews (recidivism as evaluation criterion) showed that these programmes reduce recidivism by on average 45.5 %, with rates varying from 15 % to 71 %.

To help predict the potential success of a drink-driving rehabilitation course, some 600 drivers were analysed: 300 (matched control group) who had not reoffended following such a course, against 300 who had reoffended. Based on this, the project deduced that drink-driving offenders with the following risk profile might not benefit from a driver rehabilitation course:

- those having high BAC levels at the current offence or refusing the breath test;
- those having prior drink-driving offences (i.e. the current one is not the first) and consequently having longer periods of driving licence suspension;
- those having a habitual drinking pattern in the past and, in spite of past or current periods of abstinence, having increased alcohol tolerance, therefore having felt less impaired at the time of the drink-driving offence;
- those who deny having any alcohol-related health problems, are smokers and are less aware of their own health status;
- those demonstrating an unrealistic self-perception and less self-reflection, whereby alcohol-related risks in traffic are underestimated;
- those not living in a partnership;
- those having been assessed as having an increased risk of reoffending by a qualified expert (traffic psychologist).

It was found that drink- and drug-driving rehabilitation helps to prevent people from impaired driving and restores their mobility in a safe way, and therefore driver rehabilitation should be an integrated part of a comprehensive countermeasure system. To assist with this, the project developed Europe-wide standards and recommendations of good practice for drink- and drug-driving rehabilitation measures. These were developed into a user-friendly tool (Driver Rehabilitation Evaluation Tool, DRET) for implementation, assessment or evaluation of existing or new driver rehabilitation systems or programmes. It was considered that this could be the starting point for a European networking and documentation process for driver rehabilitation measures, perhaps leading to the formulation of main procedures at an EU level.

Various recommendations were also made on the assignment of drivers to driver rehabilitation courses as follows. Legal regulation of driver rehabilitation participation should be established in order to systematically bring offenders to intervention. It is important to link participation in driver rehabilitation and licensing procedures, for example participation in driver rehabilitation as a precondition for a reduction in the suspension period or for reinstatement of the licence. Formal criteria for directly assigning drink- and drug-driving offenders to driver rehabilitation (or at least to counselling) should be established in order to initiate awareness of the problem and screen for a severe alcohol or drug problem; the criteria proposed were a high BAC level (above 1.6 g/l),

reoffending within 5 years and refusal of a test. Driver assessment prior to driver rehabilitation should be obligatory in cases in which addiction is suspected, in order to match offenders to appropriate treatment. Driver rehabilitation participation should be mandatory for high-risk offenders, repeat offenders and young (novice) drivers.

However, it was emphasised that rehabilitation options should vary according to the needs of different offenders. The intensity of intervention should increase with the severity of the problem behaviour. Addicted offenders should be at least separated from non-addicted offenders. If possible, drink- and drug-driving offenders should not be mixed. European standard group driver rehabilitation interventions can be recommended as a good practice example for non-addicted drink- and drug-driving offenders. Exchange of information between experts from driver rehabilitation interventions and addiction treatment should be encouraged. Alcohol ignition interlock programmes can be effective for drink-driving offenders in combination with rehabilitation.

As part of the DRUID project the quality-related requirements of driver rehabilitation were also considered, and it was recommended that quality management systems should be implemented at a European, national and driver rehabilitation provider level. Quality management requirements should be established on a legal base in order to achieve uniform quality management standards. It was noted that, optimally, these standards would be defined at a European level. Nevertheless, a (national) quality management body should also be installed, which is independent and authoritative and in a position to execute the operative quality management tasks in driver rehabilitation.

The details of the research and findings can be found in the deliverables from Work Package 5 — see Annex 3.

Recommendations of the project

Based on all the empirical research reviewed and carried out by the DRUID project, recommendations were formulated for policymakers in the EU and Member States as a scientific support to aid in the development of countermeasures to combat impaired driving. These recommendations are grouped according to the different classes of psychoactive substance: alcohol, illicit drugs and medicines. They are the recommendations of the project experts, and are not the official position of the European Commission.

Countermeasures to combat alcohol-impaired driving

Alcohol is still the most prevalent psychoactive substance found in drivers, a problem common to all EU Member States. The number of drivers in the general driving population with BAC > 0.5 g/l is rather low. Drivers involved in accidents (injured or killed) often have a higher BAC. The combined use of alcohol and illicit drugs or medicines is a rare but dangerous problem.

Target groups

- Young male drivers with a high BAC.
- Male drivers above 50 years of age.
- Drivers addicted to alcohol and misusing alcohol.
- Drivers combining consumption of alcohol and illicit drugs.

Legal regulations

- The legal BAC limit of 0.5 g/l, established in most European countries, is reasonable, as the risk of injury to drivers with a BAC of 0.1–0.5 g/l is rather low. There are no scientific reasons to alter this risk threshold.
- Countries in which the established legal BAC limit is lower than 0.5 g/l have, in general, a lower prevalence of alcohol-impaired drivers in the general driving population. Nevertheless, injured drivers with a high BAC are still a problem.
- The establishment of a lower legal limit for specific target groups is promising (e.g. a BAC of 0.2 g/l for novice and inexperienced drivers, as proposed in the Commission Recommendation of 17 January 2001 on the maximum permitted blood alcohol content (BAC) for drivers of motorised vehicles (notified under document number C(2000) 4397)).
- For combined consumption, lower legal limits should be imposed (e.g. 0.0 g/l BAC).
- Mandatory alcohol testing for drivers involved in accidents resulting in injury should be introduced.

Enforcement strategies

- Drink-driving enforcement is cost-beneficial. Previous efforts should be continued and, if necessary (in countries with high prevalence rates for alcohol), extended.
- The first priority of countermeasures should always be alcohol; other psychoactive substances take second place.
- To enhance the effect of general deterrence, random police checks are appropriate.

Rehabilitation measures

- Driver rehabilitation should be harmonised, for example by applying common European standards and using recommendations on good practice for rehabilitation measures developed within the DRUID project.
- Driver assessment and rehabilitation should be legally regulated and based on defined criteria.
- Drink-drivers should be treated as a separate group from drug-drivers.
- Non-addicts and addicts should be treated in separate programmes as they require different interventions or treatments.
- Multiple offenders and offenders with a BAC ≥ 1.6 g/l should undergo an examination to preclude addiction.
- An alcohol ignition interlock can be installed during the rehabilitation phase, but it should be combined with rehabilitation/treatment and close monitoring.

Licence withdrawal measures

- The practices of driving licence withdrawal should be harmonised across Europe.
- Withdrawal is an effective general and specific deterrent. Immediate withdrawal/suspension of the driving licence and a high level of perceived risk of detection are decisive. The certainty of sanction can be increased by strict enforcement (e.g. implementation of random alcohol and drug testing).
- The withdrawal duration should be between 3 and 12 months.
- Driver rehabilitation should be an integrated part of driving licence withdrawal.
- Conditional withdrawal should always be combined with rehabilitation measures and close monitoring.

Future needs of scientific investigations

- The collection of epidemiological data on a regular basis is needed to investigate the problem in the long run and to study the development of the prevalence of drink-driving. As case–control studies are very time-consuming and expensive and encounter legal and ethical restrictions, it is advisable to find alternative study methods of collecting reliable data.

Countermeasures to combat illicit drug-impaired driving

The prevalence of illicit drugs in the general driving population is much lower than that of alcohol. Across 13 countries, the estimated mean for all investigated illicit drugs is 1.9 %. Compared with alcohol (3.5 %), the prevalence of single illicit drugs is very low. THC and cocaine are the illicit substances most frequently detected in most countries. There are large national variations in prevalence.

Target groups

- Young male drivers.
- Drivers combining consumption of illicit drugs and alcohol and/or several illicit drugs.
- Drug consumers (of stimulants, e.g. MDMA) with sleep deprivation.

Legal regulations

- Regulations should be based on scientific findings; if epidemiological and experimental data are not sufficient, an expert team should determine cut-offs taking into account other findings (e.g. pharmacokinetic profiles).
- There should be European harmonisation of drug analyses (e.g. analytical cut-off limits; standardised analysing procedures).
- A risk threshold should be introduced for THC, equivalent to 0.5 g/l BAC, at 3.8 ng/ml serum, plus a value to take account of measurement errors and the confidence interval, and minus a value to take into account the metabolism between the stop/crash and sampling.
- For all other psychoactive drugs a two-tier system is advised: legal limits combined with an impairment approach. This system combines the advantages of the two legal regulations: a less severe sanction when drugs are present above the legal limit and a more severe sanction when the driver is also impaired.

Enforcement strategies

- An increase in drug enforcement is potentially cost-beneficial, especially for countries that currently have a low level of enforcement. It may not, however, be beneficial if it is implemented at the expense of drink-driving enforcement.
- The use of only those screening devices that fulfil practical and analytical criteria is advised.
- Training of police officers (drug recognition expert programmes) to improve drug detection is required.
- Drug detection roadside actions should be developed, taking into account pre-selection by time, place and target group (e.g. alcohol-impaired drivers) and national prevalence data.

Rehabilitation measures

- Driver rehabilitation should be harmonised (see Countermeasures to combat alcohol-impaired driving).
- Driver assessment and rehabilitation should be legally regulated and based on defined criteria.
- Drug-drivers should be treated as a group, separate from drink-drivers.
- Distinction should be made between non-addicts and addicts as they require different interventions or treatments.

Licence withdrawal measures

- Withdrawal in the case of drivers consuming drugs regularly should be combined with an adequate rehabilitation programme.

Future needs of scientific investigations

- Collection of epidemiological data on a regular basis is useful following implementation of new legal limits or sanctions.
- Drug recognition expert programmes and impairment checklists should be improved.
- On-site screening devices that fulfil practical as well as analytical requirements should be improved.
- Dried blood spot (DBS) analysis should be developed further.

Countermeasures to combat driving impaired by medicines

Across 13 countries, the estimated mean showed that some of the more frequently used psychotropic medicines are taken by 1.4 % of drivers (remembering that not all frequently used psychotropic medicines were screened for). The use of medicines varies considerably by country. The risk assessment reveals a medium increase in accident risk when driving under the influence of psychoactive medicines.

Target groups

- Healthcare providers and patients.
- Female drivers over 50 years old, especially drivers using benzodiazepines and medicinal opioids.

Legal regulations

- No thresholds should be defined for medicines.
- The most appropriate countermeasure to combat impaired driving is information about the possible side-effects. Therefore, a comprehensive information system for physicians, pharmacists and patients should be implemented.
- The four-level classification and labelling system developed as part of the DRUID project should be implemented.

Enforcement strategies

- These are appropriate only if medicines are misused by patients or by healthy drivers. Legal procedures and the consequences of misuse of medicines should be in line with policies combating driving under the influence of drugs.
- Strategies should focus on combined consumption of medicines and alcohol.

Rehabilitation measures

- These should be applied in cases of misuse, similar to the recommendations for combating the use of illicit drugs.

Licence withdrawal measure

- In case of misuse and combined consumption with alcohol, the recommendations are similar to those for combating the use of illicit drugs (see Countermeasures to combat illicit drug-impaired driving).

Future needs of scientific investigations

- Expand research on the impact of medicines (alone or in combination with other substances) on fitness to drive.
- Develop procedures for the assessment of fitness to drive.
- Assess the effectiveness of improved package information leaflets for moderately and severely impairing medicines.
- Develop and evaluate new ways to influence patients' intended and reported behaviour of driving under the influence of psychotropic medicines when advised not to drive during the first days or weeks of treatment.

Annex 1: Overview of the estimated European prevalence of psychoactive substances in drivers

		Inhabitants (million)	negative	amphetamines	cocaine	THC	illicit opiates	benzodiaze-pines	Z-drugs	medicinal opiates and opioids	alcohol	alcohol-drugs	drugs-drugs
Northern Europe	DK	5.4	95.52 *94.72-96.2*	0.02 *0-0.16*	– –	0.2 *0.09-0.43*	– –	0.47 *0.28-0.79*	0.32 *0.17-0.59*	0.79 *0.53-1.18*	2.53 *2.02-3.15*	0.1 *0.03-0.3*	0.06 *0.02-0.24*
	FI	5.3	97.15 *96.58-97.63*	0.05 *0.02-0.19*	0.03 *0.01-0.16*	0.04 *0.01-0.17*	– –	0.79 *0.56-1.13*	0.36 *0.21-0.6*	0.56 *0.37-0.85*	0.64 *0.43-0.94*	0.08 *0.03-0.23*	0.29 *0.16-0.52*
	NO	4.7	97.03 *96.67- 97.36*	0.06 *0.02-0.13*	0.06 *0.03-0.14*	0.48 *0.36-0.64*	– –	0.84 *0.67- 1.05*	0.69 *0.54-0.88*	0.16 *0.1-0.27*	0.32 *0.23-0.46*	0.07 *0.03-0.15*	0.28 *0.19-0.42*
	SE	9.1	98.66 *98.34-98.92*	0.07 *0.03-0.17*	– –	0.03 *0.01-0.12*	– –	0.19 *0.11-0.33*	0.31 *0.2-0.48*	0.63 *0.46- 0.86*	NA	NA	0.12 *0.06-0.25*
	Total N-EU	*93.3*	*97.32*	*0.05*	*0.02*	*0.16*	*0.00*	*0.51*	*0.40*	*0.56*	*1.20*	*0.05*	*0.17*
Eastern Europe	CZ	10.3	97.2 *96.39-97.33*	0.36 *0.17-0.72*	– –	0.46 *0.25-0.86*	– –	0.62 *0.36-1.07*	– –	0.21 *0.08- 0.52*	0.99 *0.65-1.53*	0.05 *0.01-0.28*	0.11 *0.03-0.38*
	HU	10.1	97.68 *97.04-98.18*	– –	0.04 *0.01-021*	0.19 *0.08-0.44*	– –	1.5 *1.11-2.03*	0.07 *0.02-0.26*	0.11 *0.04-0.32*	0.15 *0.06-0.38*	– –	0.27 *0.13-0.54*
	LT	3.4	94.49 *93.09-95.61*	0.22 *0.07-0.66*	– –	– –	– –	1.41 *0.9 -2.23*	– –	– –	3.86 *2.93-5.06*	0.03 *0-0.36*	– –
	PL	38.2	97.63 *97.11-98.05*	0.05 *0.01-0.18*	– –	0.57 *0.38-0.85*	0.09 *0.04-0.25*	0.14 *0.06-0.31*	– –	0.03 *0.01-0.15*	1.47 *1.14-1.9*	– –	0.02 *0-0.14*
	Total E-EU	*96.7*	*97.57*	*0.09*	*0.01*	*0.47*	*0.06*	*0.52*	*0.02*	*0.08*	*1.10*	*0.01*	*0.07*
Southern Europe	ES	44.5	85.15 *83.87-86.34*	0.11 *0.04-0.3*	1.49 *1.12-1.97*	5.99 *5.22-6.87*	0.05 *0.01-0.2*	1.4 *1.05-1.87*	– –	0.19 *0.09-0.41*	3.92 *3.3-4.66*	1.14 *0.83-1.58*	0.57 *0.36-0.89*
	IT	59.1	84.99 *82.95-86.32*	– –	1.25 *0.78-2.01*	1.15 *0.7-1.89*	0.3 *0.12-0.78*	0.97 *0.57-1.57*	– –	0.53 *0.25-1.09*	8.59 *7.19-10.23*	1.01 *0.59-1.71*	1.22 *0.75-1.97*
	PT	10.6	90.01 *89.04-90.91*	– –	0.03 *0.01-0.16*	1.38 *1.07-1.8*	0.15 *0.07-0.33*	2.73 *2.27-3.29*	– –	0.11 *0.04-0.27*	4.93 *4.29-5.64*	0.42 *0.26-0.67*	0.23 *0.12-0.44*
	Total S-EU	*128.6*	*85.52*	*0.04*	*1.23*	*3.06*	*0.19*	*1.30*	*0.00*	*0.36*	*6.43*	*1.01*	*0.87*
Western Europe	BE	10.6	89.35 *88.18-90.41*	– –	0.2 *0.09-0.43*	0.35 *0.19- 0.64*	0.09 *0.03-0.28*	2.01 *1.57-2.59*	0.22 *0.1-0.47*	0.75 *0.5-1.13*	6.42 *5.59-7.36*	0.31 *0.16- 0.58*	0.3 *0.16- 0.58*
	NL	16.4	94.49 *93.81-95.1*	0.19 *0.1-0.36*	0.3 *0.18-0.5*	1.67 *1.34-2.07*	0.01 *0-0.09*	0.4 *0.25-0.62*	0.04 *0.01-0.15*	0.16 *0.08-0.32*	2.15 *1.78-2.6*	0.24 *0.13-0.42*	0.35 *0.22-0.56*
	Total W-EU	*181.4*	*92.46*	*0.12*	*0.26*	*1.15*	*0.04*	*1.03*	*0.11*	*0.39*	*3.83*	*0.27*	*0.33*
Weighted European mean		***500.0***	***92.57***	***0.08***	***0.42***	***1.32***	***0.07***	***0.90***	***0.12***	***0.35***	***3.48***	***0.37***	***0.39***

Note: Prevalences in percentage; 95 % confidence intervals in italics.

Annex 2: Core substance list and equivalent analytical cut-off values

Substance	Whole blood (ng/ml)	Oral fluid (ng/ml)
Ethanol	0.1 g/l	0.082 g/l
6-acetylmorphine	10	16
7-aminoclonazepam	10	3.1
7-aminoflunitrazepam	8.5	1.0
Alprazolam	10	3.5
Amphetamine	20	360
Benzoylecgonine	50	95
Clonazepam	10	1.7
Cocaine	10	170
Codeine	10	94
Diazepam	140	5.0
Flunitrazepam	5.3	1.0
Lorazepam	10	1.1
3,4-methylenedioxyamphetamine (MDA)	20	220
3,4-methylenedioxy-*N*-ethylamphetamine (MDEA)	20	270
3,4-methylenedioxy-*N*-methylamphetamine (MDMA)	20	270
Methadone	10	22
Methamphetamine	20	410
Morphine	10	95
Nordiazepam	20	1.1
Oxazepam	50	13
Tetrahydrocannabinol (THC)	1.0	27
Tramadol	50	480
Zolpidem	37	10
Zopiclone	10	25

Note: THC-COOH cannot be detected in oral fluid with commonly available toxicological methods.

Annex 3: List of DRUID deliverables

All deliverables can be downloaded from the DRUID project website (http://www.druid-project.eu).

No.	Title	Content
0.1.8	Final Report: work performed, main results and recommendations	Main results of the project and evidence based conclusions and recommendations relevant for EU and Member State policy makers
Work Package 1		
1.1.1	Theoretical framework for substance effects on safe driving	Description of the theoretical framework and the methodology on how to integrate the results from the different study types (epidemiological research, experimental research, literature reviews) of WP1 and WP2
1.1.2.a	Meta-analysis of empirical studies concerning the effects of alcohol on safe driving	Meta-analysis based on 450 experimental studies published until 2007 with a total number of 5 300 findings of alcohol effects on driving performance, skills related to driving, social behaviour or mood
1.1.2.b	Meta-analysis of empirical studies concerning the effects of medicines and illegal drugs including pharmacokinetics on safe driving	Meta-analysis of empirical studies on the effects of major medicines and major illicit drugs on driving performance and on skills related to driving. In addition, dose- and time-dependent impairment curves and concentration-dependent impairment curves are provided
1.1.2.c	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	Literature reviews on the effects of opioids, narcoanalgesics and hallucinogens on driving and skills related to driving. A distinction is made between the effects caused by single administration to drug-naïve subjects and patients under chronic treatment
1.2.1	Effects of stimulant drugs on actual and simulated driving	Experimental studies conducted according to a uniform study design (road tracking tests, car-following scenario and risk-taking scenario) designed to assess the effects of dexamphetamine and MDMA on actual or simulated driving performance: MDMA (25, 50 and 100 mg) before and after sleep deprivation, MDMA (100 mg) with and without alcohol (0.5 g/l), dexamphetamine (10 and 40 mg) before and after sleep deprivation, dexamphetamine (10 mg) with and without alcohol
1.2.2	Effects of medicinal drugs on actual and simulated driving	Experimental studies conducted according to a uniform study design (road tracking tests, car-following scenario) designed to assess the effects of medicines (zopiclone, hypnotics, alprazolam, Continuous Positive Airway Pressure (CPAP) treatment, codiliprane (codeine/paracetamol), dronabinol, opioid analgesics, risperidone) on driving performance

No.	Title	Content
1.3.1	Risk estimations from different methodological approaches	Integration of the results of all epidemiological studies, experimental studies and meta-analyses conducted in DRUID. The psychoactive substances investigated in DRUID are classified with respect to prevalence and accident risk. Recommendations are given for alcohol, illicit drugs and medicines
1.4.1	Evaluation of legal measures to combat DUI/DUID	This report describes how driving under the influence of psychoactive substances can be combated effectively by legal interventions. Unlike the other deliverables, which are written from an experimental or epidemiological perspective, here a juridical perspective is taken
1.4.2	Per se limits: methods of defining cut-off values for zero tolerance	Recommendations for establishing cut-off levels for drugs in per se legislation for driving under the influence are made. Therefore, based on the authors' experience, the experience in Member States and Norway, the results of DRUID and scientific literature, this report aims at giving pertinent considerations that might be of interest for nations which want to determine per se cut-off levels
Work Package 2		
2.1.1	Prevalence of psychoactive substances in the general population	Analysis of trends in consumption of some frequently used medicines with effects on the central nervous system in a non-hospitalised EU population and the use of illicit drugs in standard age groups in Europe
2.1.2	Working paper 'Uniform design and protocols for carrying out case–control studies'	This uniform design was developed aiming to assure a representativeness of roadside surveys that were implemented in order to determine prevalence of psychoactive substances use in traffic in different countries
2.2.1	Motives behind risky driving: driving under the influence of alcohol and drugs	The deliverable describes results of in-depth interviews of Swedish drivers driven under the influence of alcohol and drugs. The aim of the study was to explore motives behind DUI/DUID in Sweden
2.2.2.	German smart-phone survey Part I: Prevalence of psychoactive substances and consumption patterns in traffic, based on a smart-phone survey in Germany Part II: Person-related characteristics of drug users and drug drivers compared to controls	The study was conducted in order to estimate prevalence of psychoactive substances within the German driving population and to identify preventive and encouraging circumstances of drug driving
2.2.3	Prevalence of alcohol and other psychoactive substances in drivers in general traffic Part I: General results Part II: Country reports	The main objective of this study was to gain solid knowledge concerning the use of psychoactive substances among drivers in European traffic. In total almost 50 000 randomly selected drivers in 13 countries were involved. Saliva samples were collected using uniform method and equipment. Samples were analysed for 23 psychoactive substances

No.	Title	Content
2.2.4	Prevalence study: main illicit psychoactive substances among all drivers involved in fatal road crashes in France	The deliverable presents results of evaluation of prevalence of drivers under the influence of alcohol and some illicit psychoactive substances for all drivers involved in fatal accidents in France, for responsible and for not responsible drivers. Prevalence was evaluated according to road user type, age and sex
2.2.5	Prevalence of alcohol and other psychoactive substances in injured and killed drivers	Results of prevalence study implemented in nine countries in two different populations (injured and killed drivers). Toxicological analyses were carried out on a total of 4 857 blood samples. Results served as reference data for the relative risk estimations
2.3.1	Relative accident risk of patients using psychotropic medicines in the Netherlands: a pharmacoepidemiological study	The aim of the case–control study presented in this deliverable was to assess the association between traffic accident risk and psychotropic medication exposure
2.3.2	Responsibility study: main illicit psychoactive substances among car drivers involved in fatal road crashes in France	The deliverable presents results of evaluation of relative risk of responsibility for fatal crashes while driving under influence of alcohol and some illicit psychoactive substances. The study was carried out in France
2.3.3	Relative risk of impaired drivers who were killed in motor vehicle accidents in Finland	The deliverable documents the results of a study carried out in Finland aiming to compare the relative risk of accident responsibility of non-impaired drivers versus that of killed drivers impaired by alcohol or some other legal psychoactive substance
2.3.4	Responsibility study: psychoactive substances among killed drivers in Germany, Lithuania, Hungary and Slovakia	Results of the study that aimed at analysing prevalence of substances used by killed drivers and estimating relative risk among fatally injured drivers responsible for fatal accident when driving under the influence of psychoactive substances
2.3.5	Risk of injury by driving with alcohol and other drugs	This deliverable presents results of studies implemented in nine countries aiming to assess the risk for a driver of being seriously injured or killed driving under the influence of psychoactive substances
2.4.1	Work Package 2 Synthesis report	The report gives a compact overview of the results and conclusions of the Work Package 2
Work Package 3		
3.1.1	Evaluation of oral fluid screening devices by TISPOL to harmonise European police requirements (ESTHER)	Methodology, implementation and results of practical evaluation of 13 oral fluid screening devices for roadside drugs detection. Evaluation was implemented by police officers under real conditions of enforcement activities. Based on the operation experience a set of Police User Requirements and Specifications (PURS) has been developed

No.	Title	Content
3.2.1	Protocol of the 'Workshop on drug driving detection by means of oral fluid screening'	Compendium of presentations and conclusions of the DRUID workshop conducted on 23 August 2009 in Geneva aiming to reconcile objectives and methods of analytical evaluation of screening devices taking into account results of practical evaluation
3.2.2	Analytical evaluation of oral fluid screening devices and preceding selection procedures	Methodology, implementation and results of analytical evaluation of eight oral fluid screening devices preselected by police officers. Performance was assessed based on sensitivity, specificity, accuracy, positive predictive value and negative predictive value for individual substances
3.3.1	Cost–benefit analysis of drug driving enforcement by the police	An assessment of the economic societal profitability of (increased) enforcement against driving under the influence of drugs together with an assessment of which of the existing devices for such enforcement are profitable
Work Package 4		
4.1.1	Review of existing classification efforts	Compilation of the existing classification system on medicines according to their influence on driving performances. In this report, the past and current systems across Europe are described and compared
4.2.1	Establishment of criteria for a European categorisation system for medicines and driving	Development of input for the establishment of a European categorisation system for medicines and driving. A proposal on the criteria and the methodology, based on expert consensus
4.3.1	Establishment of framework for classification/categorisation and labelling of medicinal drugs and driving	Evaluation of available data of medicines on the European market and subsequent assignment of categories and labels on medicines and driving. Development of fact sheets and patient-oriented information. Development of a methodology to continuously update the categorisation and labelling system
4.4.1	Classification of medicinal drugs and driving: a synthesis report	Report presents all results and conclusions of DRUID Work Package 4 in a compact form
Work Package 5		
5.1.1	State of the art on driver rehabilitation: literature analysis & provider survey	The deliverable aims at providing updated comprehensive knowledge on European driver rehabilitation (DR) best practices and comprises identification of different types of DUI/DUID offenders, options for assessment including different available approaches, existing rehabilitation programmes in and outside Europe, their scientific evidence regarding traffic safety criteria and research on addiction treatment

No.	Title	Content
5.2.1	Good practice: in-depth analysis on recidivism reasons & analysis of change process and components in driver rehabilitation courses	Reasons for recidivism concerning traffic rules offence analysed on a basis of a case–control study. Group comparison and regression analysis implemented. Analysis of change process and components of DR courses was carried out by means of a questionnaire survey developed on the basis of the TTM (Trans-Theoretical Model of Change) supplemented by the Diamond of Change
5.2.2	Development of an integrated evaluation instrument for driver rehabilitation measures	Presentation of DRET (Driver Rehabilitation Evaluation Tool), an instrument for evaluation of rehabilitation measures. Two modules (DRET-L and DRET-P) can be applied for evaluation of DR systems (L) and single programmes (P).
5.2.3	Quality management systems established along with driver rehabilitation schemes	The deliverable explains relevance and importance of quality management (QM) systems for DR activities, describes existing QM systems and evaluates them
5.2.4	Validation of existing driver rehabilitation measures	This deliverable contains recommendations with regard to DR measures developed on the basis of assessment and validation of 90 European DR programmes
Work Package 6		
6.1.1	State-of-the-art on withdrawal of driving licence: results of a questionnaire survey	The deliverable provides the comprehensive database of the legal systems as well as the practices in European countries with respect to withdrawal and re-granting of driving licenses where a withdrawal was a sanction against impaired driving, i.e. driving under influence of alcohol, illicit drugs or medicines
6.2.1	Recommendations on withdrawal	Recommendations on driving licence withdrawal/ conditional withdrawal strategies and accompanying measures
Work Package 7		
7.1.1	Review of guidelines, booklets, and other resources: state of the art	Review of the state of the art of existing information campaigns regarding psychoactive substances, as well as the documented effectiveness of those campaigns
7.2.1	Recommendations for improving medical guidelines for assessing fitness to drive in patients who use psychotropic medicines	Evaluation of existing medical guidelines for assessing fitness to drive within the framework of Council Directive 91/439/EEC on driving licenses. Overview of the current European regulations with regard to the assessment of fitness to drive and on driving performance in case patients use psychotropic medicines. Recommendations to improve prescribing and dispensing guidelines and procedures for assessing fitness to drive

No.	Title	Content
7.2.2	Guidelines & professional standards Report and CD with examples of ICT supported protocols for prescribing and dispensing of medicines affecting driving performance, and for informing patients who use psychoactive substances other than medicines	Prescribing and dispensing guidelines for selecting driving impairing medicines. Application practice guidelines and protocols in clinical decision support systems that general practitioners and pharmacists can use daily. ICT-supported protocols. Tools developed within DRUID to train general practitioners and pharmacists. Recommendations for future development of prescribing and dispensing guidelines
7.3.1	Prototypes of booklets, posters, messages for risk communication including a script for a TV-clip	Online experts survey on criteria for designing prototype documents for information regarding psychoactive substances and driving. Prototype documents for different target groups and analysis on how the documents were elaborated
7.3.2	Main DRUID results to be communicated to different target groups	Description of the risk communication theoretic frame. Assessment of pictograms in communicating risk to patients who drive under the influence of medicines. Overview of the main DRUID results with regard to the interests of the following target groups: (1) general public, (2) drivers as patients, (3) young drivers, (4) physicians and pharmacists and (5) policymakers at EU and national levels
7.4.1	Training manual for physicians and pharmacists on medicinal drugs and driving	A general overview and outlines of the relevant parts in the training courses for physicians and pharmacists (background, objectives, structure). Overview of decision-supporting ICT and non-ICT tools for assisting physicians and pharmacists in their daily prescribing and dispensing processes
7.4.2	Report on the implementation, evaluation and new technologies of practice guidelines and information materials	Evaluation of protocols and guidelines implementation (target group — healthcare professionals) using integrated (ICT) tools and non-integrated tools. Results of studies implemented in cooperation with healthcare professionals in three countries
7.4.3	DRUID outcomes and risk communication to young drivers	Results of an effort made to define appropriate risk communication measures for young drivers. A representative sample of 15- to 24-year-olds in Germany was interviewed about (a) their personal experiences and attitudes concerning driving under the influence of drugs, alcohol and/or medicines, (b) knowledge about impact of psychoactive substances and motivation to process risk communication messages and (c) media use patterns and preferences for risk message contents and channels

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The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) is one of the European Union's decentralised agencies. Established in 1993 and based in Lisbon, it is the central source of comprehensive information on drugs and drug addiction in Europe.

The EMCDDA collects, analyses and disseminates factual, objective, reliable and comparable information on drugs and drug addiction. In doing so, it provides its audiences with an evidence-based picture of the drug phenomenon at European level.

The Centre's publications are a prime source of information for a wide range of audiences including policymakers and their advisors; professionals and researchers working in the drugs field; and, more broadly, the media and general public.

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