

MEDICAMENTOS Y CONDUCCIÓN: EXPERIENCIA INTERNACIONAL

F. Javier Álvarez
Farmacología y Terapéutica,
Facultad de Medicina,
Universidad de Valladolid
alvarez@med.uva.es

MEDICAMENTOS Y CONDUCCIÓN: EXPERIENCIA INTERNACIONAL

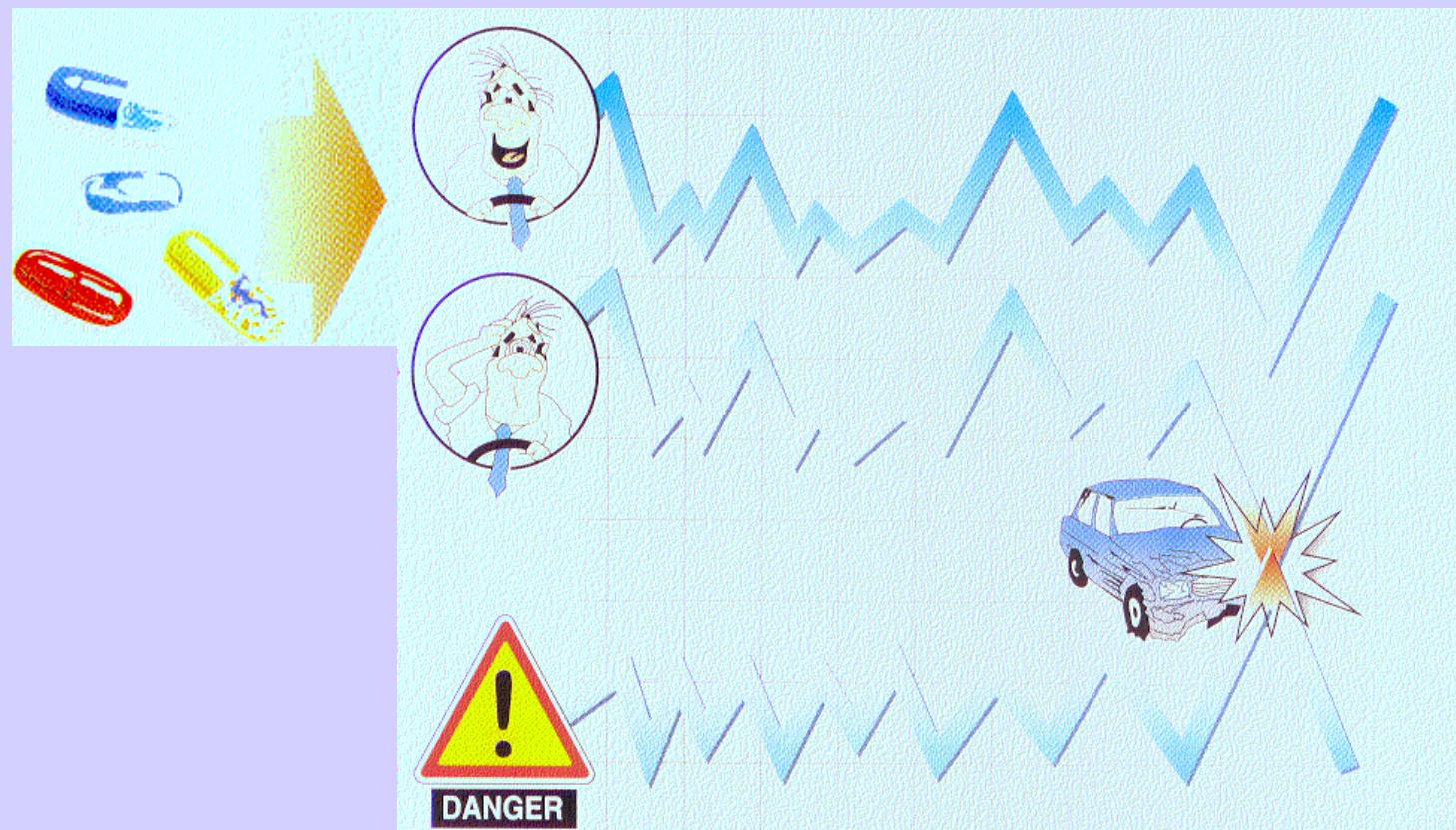
- 1. Medicamentos y seguridad vial**
- 2. Medicamentos y conducción:
¿un problema real?**
- 3. Categorización y Pictogramas:**
 - **Experiencias internacionales**
 - **Aplicación en países**

1. Medicamentos y seguridad vial

- European Commission. White Paper European Transport Policy for 2010: time to decide. Luxembourg: Office for Oficial Publications of the European Communities, 2001.
- Directorate General for Energy and Transport. Report on drugs, medicines and driving. Brussels: Directorate General for Energy and Transport, 2002.

2. Medicamentos y conducción: ¿Un problema real?

Se estima que entre el 5 y el 10% de los accidentes de tráfico pudieran deberse a que el conductor estaba bajo los efectos de la medicación.



Autores	Resultados:	RR/OR	p/95% IC
Skegg y cols, 1979 ⁹	Sedantes y tranquilizantes: Tranquilizantes menores: Tranquilizantes mayores:	RR= 5.2 RR= 4.9 RR= 6.3	p< 0.01 p< 0.01 p> 0.05
Ray y cols, 1992 ¹²	Fármacos psicoactivos: Benzodiacepinas: Antidepresivos cílicos: Antihistamínicos/analgésicos: El RR aumenta con la dosis	RR= 1.5 RR= 1.5 RR= 2.2 RR= 1.1	1.2-1.9 1.1-2.0 1.3-3.5 0.7-1.8
Leville y cols, 1994 ¹³	Benzodiacepinas: Antidepresivos cílicos: Analgésicos opioides: Antihistamínicos:	RR= 0.9 RR= 2.3 RR= 1.8 RR= 0.7	0.4-2.0 1.1-4.8 1.0-3.4 0.3-1.7
Herings, 1995 ¹⁴	Medicamentos con advertencia sobre su potencial efecto en la capacidad de conducción: Estos medicamentos fueron responsables del 3.6-7.2% de todas las muertes producidas en accidentes de tráfico y del 2.6-5.2% de todos los heridos en dicho tipo de accidentes.	RR= 1.9	p< 0.01

3. Categorización y pictograma

- **CATEGORIZACIÓN**

- Información para el profesional sanitario
 - Médico
 - Farmacéutico
 - Valoración individual (patología)

- **PICTOGRAMA**

- Información para el paciente – conductor
 - Consumo esporádico
 - Consumo habitual
 - OTC
 - Productos a partir de plantas

EXPERIENCIA INTERNACIONAL: ICADTS

The screenshot shows the homepage of the International Council on Alcohol, Drugs & Traffic Safety (ICADTS) website. The header features the ICADTS logo with a globe graphic and the text "THE INTERNATIONAL COUNCIL ON ALCOHOL, DRUGS & TRAFFIC SAFETY". The navigation menu includes links for HOME, ICADTS, EVENTS, and REPORTER. The main content area contains the ICADTS logo and the text: "THE INTERNATIONAL COUNCIL ON ALCOHOL, DRUGS & TRAFFIC SAFETY". Below this is a photograph of a car's side mirror and door handle, with a red "D" shape overlaid on the image. A sidebar on the right contains the text: "The International Council on Alcohol, Drugs and Traffic Safety (ICADTS) is an independent nonprofit body whose only goal is to reduce mortality and morbidity brought about by misuse of alcohol and drugs by operators of vehicles in all modes of transportation. To accomplish this goal, the Council sponsors international and regional conferences to collect, disseminate and share essential information among professionals in the fields of law, medicine, public health, economics, law enforcement, public information and education, human factors and public policy." At the bottom of the page is a footer with the text "THE INTERNATIONAL COUNCIL ON ALCOHOL, DRUGS & TRAFFIC SAFETY" and links for CONTACT and LINKS.

ICADTS (2001)

Category	Description	~ BAC (g/l)
I	Presumed safe or unlikely effect	< 0,5
II	Likely minor or moderate effect	0,5 – 0,8
III	Likely severe effect or presumed dangerous	> 0,8

Alvarez FJ, De Gier JJ, Chistophersen AS, Del Río MC, Donelson AC, Karlovsek MZ, Maes VA, Morland J, Mercier-Guyon Ch, Ogden EJD, O'Hanlon JF, Verstraete AG, Walsh JM.
Prescribing and dispensing guidelines for medicinal drugs affecting driving performance.
Utrecht: International Council on Alcohol, Drugs and Traffic Safety, 2001
<http://raru.adelaide.edu.au/icadts/reports/ICADTSpresguiderpt.pdf>

GUÍA DE
PRESCRIPCIÓN
FARMACOLÓGICA
Y SEGURIDAD VIAL



MINISTERIO
DEL INTERIOR

Dirección Gen. de Tráfico

GUÍA DE
PRESCRIPCIÓN
FARMACOLÓGICA
Y SEGURIDAD VIAL



MINISTERIO
DEL INTERIOR

Dirección Gen. de Tráfico

Categoría	Definición	Fármaco
I	Improbable producción de efectos adversos sobre la capacidad de conducción: existe evidencia experimental repetida de la inexistencia de alteraciones en la capacidad de conducción o relacionada con ella.	Astemizol 10mg Terfenadina 60 mg Loratadina 10 mg
II	Possible producción de efectos adversos leves o moderados relacionados con la capacidad de conducir: existe evidencia experimental de alteración en la capacidad de conducción o relacionada con ella.	Difenhidramina 25 mg Terfenadina 120 mg Cetirizina 20 mg Clemastina 1 mg
III	Fácilmente producen efectos adversos graves relacionados con la capacidad de conducción: existe evidencia experimental repetida.	Prometazina 25mg Tripolidina 2,5 mg

N.º 4 Octubre 2004

JANO

MEDICINA DE TRÁFICO Y HUMANIDADES



Hematología y conducción de vehículos

Nefropatías y conducción de vehículos

Diabetes mellitus y otros trastornos endocrinometabólicos y la conducción de vehículos

Anamnesis y valoración del consumo de alcohol y problemas relacionados con el alcohol en los Centros Médicos de Reconocimiento de Conductores

Anamnesis y valoración del consumo de medicamentos en los centros médicos de reconocimiento de conductores. Principios de la prescripción racional de medicamentos al paciente conductor de vehículos

Actividad acreditada por la Comisión de Formación Continuada del Sistema Nacional de Salud con 7,6 créditos

DOYMA

Manual sobre

aspectos médicos

relacionados con la capacidad de
CONDUCCIÓN
de **VEHÍCULOS**



Ministerio del interior



Dirección Gral. de Tráfico

DRUID

UNIVERSIDAD DE VALLADOLID

LA SOMNOLENCIA, LA FATIGA Y LAS DISTRACCIONES
SON LA CAUSA DE UNO DE CADA TRES ACCIDENTES DE TRÁFICO.

INTERRUMPE TU VIAJE, NO TU VIDA.

SI ESTÁS CANSADO NO CONDUCZAS

NO USES EL MÓVIL AL VOLANTE

ATENCIÓN A LOS MEDICAMENTOS

NO BEBAS ALCOHOL



Dirección General de Tráfico

TÚ SÍ PUEDES EVITARLO.



DRUID PROJECT – WP4

**Work package 4: Classification
(Categorization of Medicines on Driving)**

**Progress in the categorization and labelling of
medicines impairing driving ability**



[About DRUID](#)
[Work Packages](#)
[Deliverables List](#)
[Partner](#)

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Internal Area

>Homepage

Welcome to DRUID

The Integrated Project DRUID (Driving under the Influence of Drugs, Alcohol and Medicines) deals with the scourge of drink-driving and is going to find answers to questions concerning the use of drugs or medicines that affect people's ability to drive safely. DRUID will bring together the most experienced organisations and researchers throughout Europe, involving more than 20 European countries. The aim is to gain new insights to the real degree of impairment caused by psychoactive drugs and their actual impact on road safety. All in all this Integrated Project will fill the gaps of knowledge and provide a solid base to generate harmonised, EU-wide regulations for driving under the influence of alcohol, drugs and medicine.

**bast**

DRUID

The European Integrated Project DRUID is a part of the 6th Framework Programme. It brings together 36 institutes from 18 European countries.
 Start: October 15th, 2006
 Duration: 48 months

News



DRUID General Meeting 2008: Members of the Steering Committee in front of the BAST

Links

[>> European Commission](#)
[>> 6th Framework Programme](#)

**About DRUID****Work Packages****1: Methodology****2: Epidemiology****3: Enforcement****4: Classification****5: Rehabilitation****6: Withdrawal****7: Dissemination****Overview****Deliverables List****Partner****Search****Internal Area**>[Homepage](#) >[Work Packages](#) >4: Classification

Work Package 4 - Classification

Work Package-leader: Javier Alvarez, Universidad de Valladolid, Spain

A large proportion of the population habitually drives while taking medicinal drugs (either in acute or chronic use). While medicinal drugs are not the main factor to be considered when looking at the causes of road traffic accident, their importance is continually growing. In that way, the White Paper "European Transport Policy for 2010: time to decide" aims to reduce the accident mortality rate by 50 % by 2010. To this end, the White Paper addresses the issue of "to combat the scourge of drink-driving and find solutions to the issue of drugs and medicines".

The prescription of medicinal drugs is an everyday factor in clinical practice, and even though safer and more effective medicinal drugs are being commercialized every day, some of them can deteriorate psychomotor performance, which can affect a person's ability to drive safely.

The work package classification will have an output both for physicians/pharmacists and other health professionals, as well as the patients taking these medicinal drugs, by two major actions: categorization of the medicinal drugs on driving ability, and propose appropriate labelling systems regarding medicinal drugs and driving.

This Work package has four objectives:

1. To review of the existing i) classification/categorisation systems and ii) labelling systems regarding medicinal drugs and driving.
2. To propose and agree on the criteria and the methodology on the establishment of a European i) classification/categorisation system and ii) labelling system of medicinal drugs and driving.
3. To develop of a methodology to continuously update the i) classification/categorisation system and ii) labelling system on medicinal drugs and driving.
4. To propose of a classification/categorisation system for the relevant therapeutic groups of medicines available in the market.

For the achievement of these objectives work package 4, has issued three research tasks.

Tasks 4.1, Review of existing classification efforts, will focus on the first objective. As a background, this task will use the current Belgian, Spanish and French categorization systems on





DRUID PROJECT – WP4

Task 4.2. The establishment of criteria for a European Categorization, based on consensus

- RUGPha (The Nederland) is the Task Leader.
- Task 4.2 start 15 November 2007
- AIM: to propose and agree on the criteria and the methodology on the establishment of a European classification/categorization system and labelling system of medicinal drugs and driving.
- Deliverable 4.2. will be available on month 39 (January 2010).



DRUID PROJECT – WP4

Task 4.2. The establishment of criteria for a European Categorization, based on consensus

- Workshop 27th-28th February 2008 Paris [EMEA Pharmacovigilance Working Party] Visit-Meeting AFSSAP: 27th February 2008 Paris [experience with the categorization system in France]
- Workshop 12th-13 June 2008 Den Haag [EMEA Pharmacovigilance Working Party] [information on the Dutch campaign]
- Workshop 10th-11th November 2008 Lisbon [EMEA Pharmacovigilance Working Party]
- Foreseen EMEA meeting, September 2009.



London, 14 December 2007
Doc. Ref. EMEA/566951/2007

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

DRAFT

PROPOSAL FOR A REVISION OF THE EUROPEAN COMMISSION GUIDELINE ON
SUMMARY OF PRODUCT CHARACTERISTICS

This consultation applies to the proposed changes from Revision 1. These changes are highlighted in the text. This revision mainly aims to reflect new requirements in relation to the paediatric regulation and to further clarify guidance for some sections e.g. section 4.8 on undesirable effects.

TRANSMISSION TO CHMP	December 2007
ADOPTION BY CHMP FOR RELEASE FOR CONSULTATION	10 December 2007
END OF CONSULTATION ON PROPOSED CHANGES (DEADLINE FOR COMMENTS)	<i>28 March 2008</i>

Comments should be provided using this [template](#) and sent to MISecretariat@emea.europa.eu or by Fax: +44 20 75 23 71 29, by 28 March 2008.

Public
consultancy
on the
Writing on
SPC

4.7 Effects on ability to drive and use machines:

- On the basis of the pharmacodynamic and pharmacokinetic profile, reported adverse reactions and/or specific studies in a relevant target population addressing the performance related to driving and road safety or using machines, specify whether the medicinal product has a) no or negligible influence b) minor; c) moderate influence or d) major influence on these abilities. Effects of the disease itself on these abilities should only be discussed in exceptional circumstances. Other important factors that affect the ability to drive and use machines should be considered if relevant, e.g. duration of the impairing effect and the development of the tolerance of adverse reactions with continued use. For situations b, c and d, special warnings/precautions for use should be mentioned



DRUID PROJECT – WP4

Task 4.3. Establishment of framework for classification/categorization and labelling of medicinal drugs and driving

- UVa (Spain) is the Task Leader.
- Task 4.3 start 15 September 2007
- AIM: To propose of a classification / categorization system for the relevant therapeutic groups of medicines available in the market,
- AIM: To develop of a methodology to continuously update the classification/categorization system and labelling system on medicinal drugs and driving.
- Deliverable 4.3 will be available on month 45 (July 2010)



DRUID PROJECT – WP4

AGREEMENT ON 4 CATEGORIES FOR CATEGORIZATION ON MEDICINES AND DRIVING

- No or negligible influence
- Minor influence (category I)
- Moderate influence (category II)
- Major influence (category III)

FOR THE LABELLING WE AGREE ON THREE
LEVELS

Warning for patients <<with warning symbols and standard descriptions per country>>

[no warning needed]

Warning level 1

Do not drive without having read the relevant section on driving impairment in the leaflet.

Warning level 2

Do not drive without advice of a health care professional. Read the relevant sections on driving impairment in the leaflet before consulting the physician or pharmacist

Warning level 3

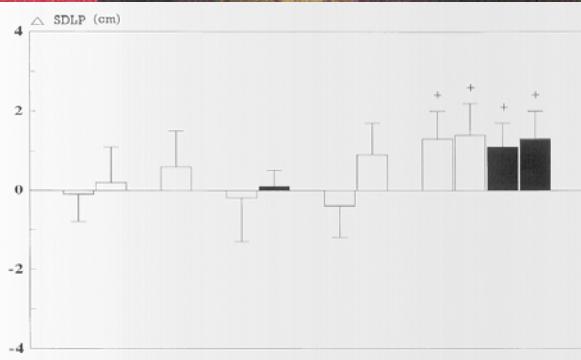
Do not drive. Seek medical advice after a period of treatment about the conditions to restart driving again.



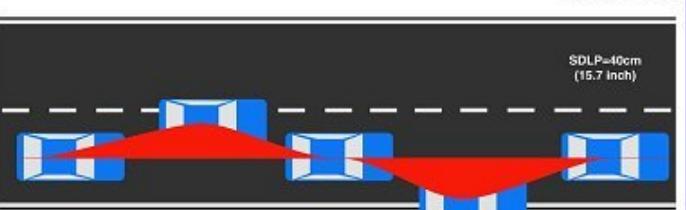
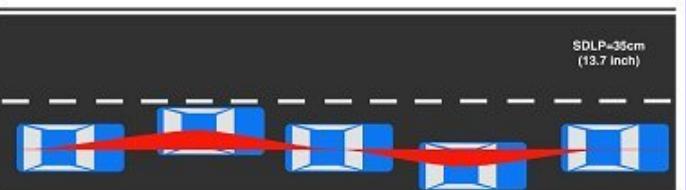
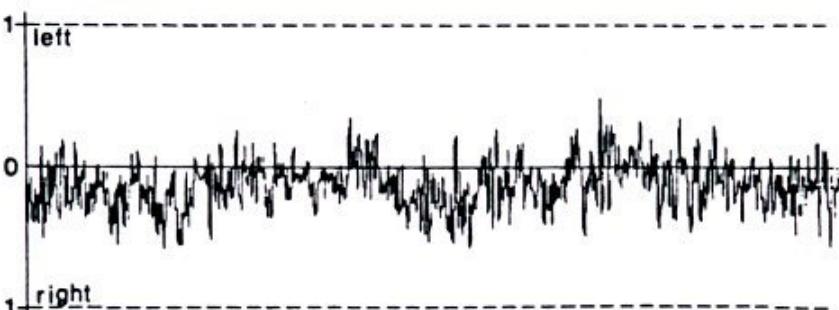
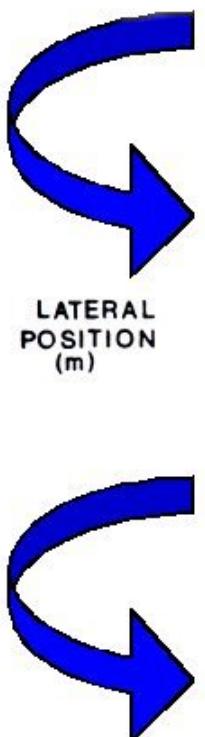
DRUID PROJECT – WP4

INFORMATION FOR EACH MEDICINE: FACT SHEET

- 1: INFORMATION REGARDING THE NEW FILENAME AND DATE OF PRODUCTION - REVIEW
- 2: MEDICINE BEING EVALUATED
- 3: SOURCE OF INFORMATION:
- 4: PRESENTATIONS:
- 5: INDICATIONS:
- 6: POSOLOGY AND METHOD OF ADMINISTRATION:
- 7: PHARMACODYNAMIC PROPERTIES:
- 8: PHARMACOKINETIC PROPIERTIES:
- 9: POSSIBLE SIDE EFFECTS RELATED TO DRIVING:
- 10: SPC SECTION 4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:
- 11: LEAFLET SECTION ON DRIVING: DRIVING AND USING MACHINES:
- 12: STUDIES ON PSYCHOMOTOR PERFORMANCE AND RISK STUDIES:
- 13: CATEGORIZATION IN SOME EU COUNTRIES:
- 14: PROPOSED CATEGORIZATION:
- 15: INFORMATION FOR THE PATIENT:
- 16: PLACE AND DATE OF AGREEMENT BY THE WP4 MEMBERS:



The instrumented test vehicle has a camera for lateral position measurements. The camera is equipped with two infrared lights, to enable recording during the night and dark weather circumstances. Data (speed and lateral position) are continuously recorded on a board computer with a sampling rate of 2 Hz. The raw data is edited off-line to remove data that were disturbed by extraneous events (e.g. overtaking and traffic jams).



The Standard Deviation of Lateral Position (SDLP) is computed, expressing the weaving of the car.

TIME (h)	1.2	3-4	3-4	1.2	1.2	1.2	3-4	2-3	4-5	2-3	4-5
DAY	1	1	1	1	4	1	1	1	1	4	4
LORATADINE				10 mg (lx)		10 mg qd		20 mg (lx)		20 mg qd	
SUBJECTS	20 M	8 M & 8 F		16 M		20 M		14 M & 10 F			
REF.	(11)	(9)		(11)		(11)		(10)			



DRUID PROJECT – WP4

EMEA categorization on frequency of undesirable effects

- **Very common** ($>1/10$)
- **Common** ($>1/100, <1/10$);
- **Uncommon** ($>1/1,000, <1/100$);
- **Rare** ($>1/10,000, <1/1,000$);
- **Very rare** ($<1/10,000$),
- **Not known** (cannot be estimated from the available data, since no valid estimate can be derived from clinical trials or epidemiological studies).

DRUID PROJECT – WP4

System organ class	Selection of undesirable effects that can impair the ability to drive safely
Nervous system disorders	<ul style="list-style-type: none"> ▪ Somnolence, dizziness, drowsiness ▪ Confusion - cognitive disorder- disorientation ▪ Involuntary movement disorders: ataxia, tremor, Parkinsonism, acute dystonic (dyskinesia) and dyskinetic reactions (dystonia) ▪ Convulsions -seizures
Psychiatric disorders	<ul style="list-style-type: none"> ▪ Perception disturbances (hallucination, visual hallucination, auditory hallucination, illusion) ▪ Psychotic reactions and psychotic disorder (including paranoia psychosis) ▪ [Other: Emotional lability, mood swings, aggression, nervousness, irritability, personality disorders, thinking abnormal, abnormal behaviour, euphoric mood, restlessness (emotional state of excitement), depersonalisation]
Eye disorders	<ul style="list-style-type: none"> ▪ Diplopia or double vision, ▪ Blurred vision ▪ Accommodation disorders ▪ Visual acuity reduced ▪ Photophobia ▪ [Other: visual field defect, peripheral vision loss, altered visual depth perception, oculogyric crisis].
Ear and Labyrinth disorders	<ul style="list-style-type: none"> ▪ Vertigo ▪ Hearing loss ▪ [Other: buzzing, tinnitus]
Metabolism and nutrition disorders	<ul style="list-style-type: none"> ▪ Hypoglycaemia

N03 ANTIEPILEPTICS			CATEGORY	LABELLING
N03A	Antiepileptics			
N03AA	Barbiturates and derivatives			
	N03AA02	Phenobarbital **** Oral administration **** Parenteral administration	III III	III III
	N03AA03	Primidone	III	III
N03AB	<i>Hydantoin derivatives</i>			
	N03AB02	Phenytoin **** Oral administration **** Parenteral administration	III III	III III
	N03AB05	Phenytoin Combinations	III	III
N03AD	<i>Succinimide derivatives</i>			
	N03AD01	Ethoxusimide	II	II
N03AE	<i>Benzodiazepine derivatives</i>			
	N03AE01	Clonazepam **** Oral administration **** Parenteral administration	II III	II III
N03AF	<i>Carboxamide derivatives</i>			
	N03AF01	Carbamazepine	II	II
	N03AF02	Oxcarbazepine	II	II
	N03AF03	Rufinamide	II	II
N03AG	<i>Fatty acid derivatives</i>			
	N03AG01	Valproic acid **** Oral administration **** Parenteral administration	II III	II III
	N03AG04	Vigabatrin	II	II
	N04AG06	Tiagabine	II	II
N03AX	<i>Other antiepileptics</i>			
	N03AX09	Lamotrigine	II	II
	N03AX11	Topiramate	II	II
	N03AX12	Gabapentin	II	II
	N03AX14	Levetiracetam	II	II
	N03AX15	Zonisamide	II	II
	N03AX16	Pregabalin	II	II
	N03AX18	Lacosamide	II	II



DRUID PROJECT – WP4

NEW DRUGS IN THE MARKET: MEDICINES GRANTED FOR EMEA
JANUARY 2008- APRIL 2009

Approved 52 medicines

ATC A ALIMENTARY TRACT AND METABOLISM-----	3
ATC B BLOOD AND BLOOD FORMING ORGANS-----	4
ATC C CARDIOVASCULAR SYSTEM-----	4
ATC G GENITO URINAY SYSTEM AND SEX HORMONES-----	2
ATC J ANTIINFECTIVES FOR SYSTEMIC USE-----	10
ATC L ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS-----	11
ATC M MUSCULO-SKELETAL SYSTEM-----	2
ATC N NERVOUS SYSTEM-----	7
ATC S SENSORY ORGANS-----	1
ATC V VARIOUS-----	2
Code not yet assignet-----	6



DRUID PROJECT – WP4

Herbal preparations and general information for the patient:

N05CM

Humulus lupulus (Lupulo)
Melissa officinalis (Melisa)
Passiflora incarnata (Pasiflora)
Valeriana officinalis (Valeriana)
Eschscholtzia (Amapola de california)
Lippia citriodora (Hierbaluisa)
Lavandula angustifolia (Lavanda)
Tilia cordata (Tila)
Piscidia erythrina (Piscidia)
Espino blanco (crataegus oxyacantha)

N06A

Hiperico (hypericum perforatum)

N06DX02

Ginkgo (ginkgo biloba)

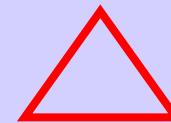
AUSTRIA, RUMANIA



DINAMARCA, ESTONIA, ISLANDIA Y NORUEGA



LETONIA, POLONIA



ESLOVENIA



FRANCIA



Warning sign	Country (year) Description
	FRANCE (1999)
	Old warning label for driving impairing medication in France (1999)
	FRANCE (2005) [8]
 NIVEAU 1	Be careful. Do not drive without having read the leaflet.
 NIVEAU 2	Be very careful. Do not drive without advice of a medical professional.
 NIVEAU 3	Attention: danger: Do not drive.
	SPAIN (2007)[9]
 Conducción: ver prospecto	Driving: Please read the leaflet or package insert.