

**Prescribing and Dispensing
Guidelines for Medicinal Drugs
Affecting Driving Performance**
(FDA/NTSB Joint Public Meeting)

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- Experts from 8 countries (USA, Europe, Australia)
- Multidisciplinary approach (change of behavior)
- Sharing responsibilities (pharmaceutical industry, drug regulatory authorities, health educators, driving instructors, and patients)

Drug Regulatory Authorities

- Implement warning systems that are effective
- Discuss with health care professionals, drug manufacturers and patients how a three-tier categorization system could be used
- Improve the structure to assist drug manufacturers in drug testing that will allow categorization of medicinal drugs
- Establish an independent center for maintaining the categorization system

Three-tier Categorization System

Category	Impairment description	Comparison with BAC
I	Presumed to be safe or unlikely to produce an effect	Equivalent to BAC < 0.2 g/l (< 0.02%)
II	Likely to produce minor or moderate adverse effects	Equivalent to BAC 0.2-0.5 g/l (0.02-0.05%)
III	Likely to produce severe effects or presumed to be potentially dangerous	Equivalent to BAC >0.5 g/l (> 0.05%)

Relative risks of injurious road accidents associated with the use of hypnotic and anxiolytic drugs

Drug	Relative Risk	Comparable to BAC (%)	Reference
Diazepam	3.1	0.075	Neutel, 1998
Flurazepam	5.1	0.095	Neutel, 1998
Lorazepam	2.4	0.070	Neutel, 1998
Oxazepam	1.0	<0.050	Neutel, 1998
Triazolam	3.2	0.075	Neutel, 1998
Zopiclone	4.0	0.080	Barbone et al, 1998

Dose-response Relationship for Benzodiazepines

Odds ratio for traffic accident by dose:

Low dose		Intermediate dose		High dose	
N	Odds ratio (95% CI)	N	Odds ratio (95% CI)	N	Odds ratio (95% CI)
63	1.27 (0.80-2.01)	84	1.68 (1.13-2.49)	42	2.67 (1.33-5.39)

Barbone et al, 1998

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Professional Organizations of Physicians and Pharmacists

- Discuss and propose joint efforts for improving prescribing and dispensing practices (key-messages to change attitudes)
- Encourage membership to prescribe and dispense the least impairing or safe drug
- Utilize ICT for implementing guidelines and for documentation of patients' experiences

Authorities with Responsibilities in Transportation Safety and Public Health

- Present evaluations on warning systems
- Review knowledge regarding relative risk of accidents by users of medicinal drugs
- Discuss development of new regulations
- Encourage health care professionals to implement practice guidelines
- Media campaigns (focus on changing roles)

Driving Licensing Authorities

- Meet their obligation for applicant's fitness to drive when issuing or renewing driving licenses
- Develop effective lines of communication with medical and pharmaceutical practitioners

Research and Education

- Research institutes and organizations in the field of drugs and driving: disseminate information on the safe use of medicinal drugs by drivers via the Internet, addressing both the public and professional
- Medical and pharmacy schools: develop educational programs pertaining to drugs and driving based on present knowledge