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The experience with the categorisation of medicinal drugs in Belgium

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Parallel to the introduction of a new legislation on illicit drugs and driving in Belgium in 1999, the Secretary of State for Safety organised an information campaign on medicines and driving, which was conducted at different levels. About 180 medicinal substances, available in Belgium (1997) and belonging to therapeutic classes susceptible of impairing driving performance (hypnotics-sedatives-anxiolytics, anticonvulsants, antidepressants, neuroleptics, narcotics, antihistamines, beta-blockers, central stimulants and antidiabetics), were classified on the basis of literature data from about 500 references. The molecules were categorised using the system proposed by Wolschrijn et al.: 7 classes ranging from no effect (I) through minor and moderate (II.1 and II.2) to severe effects (III), completed with the respective * categories (I*, II*, III*) for classes with insufficient scientific data (classes presumed on the basis of the pharmacological profile and the analogy with more documented molecules)[1].
The classification of the substances proved to be problematic due to the lack of study data (42% of the substances in presumed categories) and the diversity of the study protocols. As the effect of the drug is dose dependent and time-related, the assignment of one category per drug is often inadequate.
The results of the categorisation were disseminated through three documents:

- In a scientific report, literature data of 179 medicines were compiled with categorisation in 7 classes according to their impairing effect. This report was submitted to the concerned pharmaceutical companies. Most reacted positively and co-operated in the project, although commercial arguments sometimes complicated the discussions. The scientific report could be ordered, but only few orders were received (252 copies in the first 4 months).
- The scientific study was condensed to a 32-page brochure for physicians and pharmacists with the categorisation of the drugs and practical guidelines when prescribing and dispensing medicines. All physicians and pharmacists received the professional brochure (65000 copies were distributed).
- A general public brochure contained general information, guidelines and warnings for patients taking medicines. It was printed in 500000 copies and distributed in pharmacies and doctor's offices. Both brochures can be downloaded in PDF format from the websites in references 2 and 3, respectively in Dutch and French.

The campaign was introduced by a press conference and covered by TV spots and the Internet. Both brochures proved to be a success with great interest from public and (non)-professionals. Since that time no further initiatives were taken, apart from some continuing medical education for physicians and pharmacists. The campaign was not evaluated, but based on some informal contacts, its impact seems to have been limited.
There have been plans to actualize the list and to perform a similar information campaign. In addition, the Federal government wants to implement a pictogram on the package of medicinal drugs (in consultation with the other EU states), a modification of the package insert and the sensibilisation of the prescribing physicians. Further work will be carried out in the European DRUID project.

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