Progress In The European Union On The Application Of Lists Of Medicinal Drugs That Impair Driving.

A.G. Verstraete

Laboratory of Clinical Biology– Toxicology, Ghent University Hospital, Belgium

Keywords
Medicine, pictogram, driving, legislation, prevention

Abstract
In Europe, slow progress is made towards the categorization of medicines. At the European Union level, the working group on Alcohol, drugs, medicines and driving has recommended implementation of a categorization system on the effects of medicinal drugs on driving performance, establishment a 'minimum' list of medication that clearly impair ability to drive, development of guidelines for prescribing medicinal drugs to the driving patient, for the information to be provided to the driving patient by physicians, pharmacists and for information to the general public as regards the effects of medicinal drugs on driving and implementation of a pictogram in the package insert and on the package of drugs that clearly impair the ability to drive safely.
In the latest version of the Third Road Safety Action Plan does not mention medicine categorization explicitly.
In several member states, there has been some progress, but also setbacks. As the situation in Spain and France is described by other authors, it will not be reviewed here. In Sweden, the system of the red triangle was suspended, because of the risk that packages requiring the pictogram, directly imported from other countries where there is not such a system, would lack the pictogram and introduce confusion. In Belgium, no initiatives have been taken to update the list that was established in 1998-1999. However, in the drug action plan of the federal government, adopted early 2001, includes implementation of a pictogram (in consultation with the other EU states), a modification of the package insert and the sensibilization of the prescribing physicians.
In conclusion, countries having a system with a red triangle, are unhappy about it, and countries that don’t have it, would like to introduce it. A lot of efforts are still needed in order to implement a categorization system in Europe.

Introduction
Different approaches are possible for reducing the danger of driving under the influence of medicinal drugs. One of the most important is prevention. Patients must be warned of the dangers of driving under the influence of certain drugs. This can (and should) be done by the prescribing physician and by the pharmacist who dispenses the medicines. The summary of product characteristics or package insert contains a warning (if applicable) but experience has
shown that it is often very vague and not informative. To draw the attention of the patient, a pictogram can be printed on the package.
In Europe, eight countries (the five Nordic countries, Austria, The Netherlands and France) have a warning pictogram, and the experience has not been very good. This pictogram is a red triangle in the Nordic countries, a red triangle with a black car in France, and a sticker that can be used by the pharmacist in the Netherlands.
For the information of physicians and pharmacists, a categorization system of medicines, according to the impairment they cause would be a great help.
An ICADTS working group has recently made recommendations [1], which are detailed in other contributions. The aim of this article is to describe the recent evolution in different European countries.

In Belgium, there has not been much evolution. In 1999, a categorization system was proposed [2], a leaflet was distributed to the public, and a 32-page brochure was distributed to all pharmacists and physicians. However, the effects of this campaign have not been measured. There are plans to actualize the list and to do a similar information campaign. In addition, as part of its policy on drugs, 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 sensibilization of the prescribing physicians.

In Denmark, the list of medicines that has the red triangle is available on the Internet at http://www.medicinpriser.dk/trafikfarlig.cfm. This list is updated every two weeks.

As the situation in France is described elsewhere, only a short overview will be given here. In France, the pictogram was introduced in May 2000. The experience has not been very good, as out of precaution, many pharmaceutical companies have added the pictogram to their package, and now more than 50% of the medicines carry a pictogram. Moreover, in some cases (e.g. buprenorphine (Subutex®)) , an AMM (Agence du médicament) number is printed just under the pictogram, which is interpreted by many as if the agence du médicament has given a derogation and driving is allowed while using this medicine. Another interesting initiative is the printing of the first of a series of brochures on medicines and driving. This first brochure covers allergy and is written by a clinician and a traffic safety expert [3].

In The Netherlands, in preparation for the new law on driving under the influence, discussions have taken place on which drugs to mention in the law (e.g. long-acting benzodiazepines would be forbidden, tricyclic antidepressants and short-acting benzodiazepines only when taken in high dosages), and some proposals were made for blood levels.

In Norway, educational programs for physicians and pharmacists, regarding prescribing and dispensing guidelines for medicines that impair driving performance, have been set up.

In Spain, a guide to prescription of medicines, taking into account traffic safety, has been published [4]. It contains a categorization of medicines.

In Sweden the system of the red triangle was suspended, because of the risk that packages requiring the pictogram, directly imported from other countries where there is not such a system, would lack the pictogram and introduce confusion.
In the **United Kingdom**, there have been discussions between driving licensing and drug regulatory agencies regarding improving labeling, information provision and the possibility of a campaign to publicize the dangers of driving under the influence of medicines. As is the case in Belgium, new EU requirements will be awaited before a pictogram is implemented.

At the **European Union** level, the working group on Alcohol, drugs, medicines and driving has made the following recommendations:

- Implementation of a categorisation system on the effects of medicinal drugs on driving performance;
- Establishment of a 'minimum' list of medications that clearly impair the ability to drive;
- Development of guidelines for prescribing medicinal drugs to the driving patient;
- Development of guidelines on the information to be provided to the driving patient by physicians and pharmacists as regards the effects of medicinal drugs on driving;
- Development of guidelines on the information to be provided to the general public as regards medicinal drugs and driving;
- A harmonised pictogram (same symbol in all Member States) could be imposed for all cases where a medicinal product has an effect on the ability to drive vehicles or to operate machinery;
- Detailed information should be provided in the package leaflet and in the Summary of Product Characteristics. The “guideline on the readability of the label and package leaflet of medicinal products for human use” could be amended in order to substantiate this proposal. Attention should be paid to the fact that the warning should be detailed and contain substantive information (following an evaluation of the risks) and not just global standard sentences.

Among the five recommendations for medicines, the following two concern categorization and warning systems:

- To inform users with appropriate and harmonised labelling or pictograms on medicine packages.
- To implement a Europe-wide classification of medicinal drugs, based on:
  - the pharmacological effects of the drugs
  - their therapeutic indications
  with regard to the different categories of driving licences and the decisions of the medical authorities for driving licences.

In the text supporting the recommendations, a list of the main campaigns dealing with medicinal drugs and driving within the European Union since 1995 has been compiled. In the first deliverable of the Rosita Project [5], A comparison is made between seven different categorization and warning systems in Europe.

In the latest version of the Third Road Safety Action Plan does not mention medicine categorization explicitly. However, warning labels on medicines are mentioned in the communication from the commission to the council, the European Parliament, the Economic and Social committee and the Committee of the Regions on Priorities in EU road safety, Progress report and ranking of actions (Com(2000) 125 final).

**Conclusion**

Relatively little progress has been made in the last three years in Europe. Some new categorizations lists have been published, but there also have been setbacks like the suspension of the warning system in Sweden. It still remains true that countries having a pictogram, are unhappy about it, and countries that don’t have it, would like to introduce it. In
order to progress, consensus should emerge on the number of classes that exist in the categorization system (2, 3 or 4), the design of the pictogram, and the criteria for printing a pictogram on a package. When these aspects are decided, the regulatory agencies will have to be convinced to implement the system on a European level.

References

1. ICADTS working group on Prescribing and dispensing guidelines for medicinal drugs affecting driving performance. Prescribing and dispensing guidelines for medicinal drugs affecting driving performance. ICADTS, 2001


5. Maes V, Charlier C, Grenez O et al. Deliverable D1. Drugs and medicines that are suspected to have a detrimental impact on road user performance. Rosita consortium, Gent, 1999