

**Question for written answer P-000024/2013  
to the Commission  
Rule 117  
Toine Manders (ALDE)**

**Subject:** European classification system for medicines based on risks of impairment of driving ability

DRUID, Driving under the Influence of Drugs, Alcohol and Medicines ([www.druid-project.eu](http://www.druid-project.eu)<sup>1</sup>), has issued a number of scientifically based recommendations for improving information in medicine package leaflets for patients who are taking medicines that impair driving ability but who wish to drive.

They were compiled after discussions with the Pharmacovigilance Working Party of the EMA, the European registration authority of the European Medicines Agency. The findings from the studies constitute a sound basis for establishing a harmonised, EU-wide framework for providing information on driving under the influence of medicines; they also consider scientific evidence and best practices in the Member States and look at the information which patients should receive in medicine package leaflets and which should be given to prescribers and pharmacists.

The working party, consisting of researchers from renowned universities and institutions in more than 20 Member States, examined various labelling systems in the Member States, taking this as a basis for devising a framework with standardised wordings for package leaflets, warning levels, symbols and pictograms. The recommendations comprise a classification system for medicines with a labelling system for the classification of risks of impairment of driving ability.

It has now emerged that other bodies too are asking questions about the failure to implement a European classification system properly. An association of national medicines databases from various Member States has indicated that implementation is necessary in all Member States in order to be able to apply the data for the whole of Europe and keep up-to-date information on both new and existing medicines.

1. Is the Commission familiar with the DRUID project and the cooperation with the EMA to develop a European classification system for medicines which affect driving ability? If not, why not?
2. Why do initiatives such as DRUID fall not under DG SANCO but under DG MOVE at the Commission, bearing in mind that the European public health aspect clearly plays a greater role in them than European road safety?
3. Will the Commission consider adopting the proposal for European harmonisation of the classification of medicines which affect driving ability? If not, why not?

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<sup>1</sup> [http://www.druid-project.eu/cln\\_031/nn\\_107548/Druid/EN/deliverables-list/downloads/Deliverable\\_4\\_2\\_1,templateId=raw,property=publicationFile.pdf/Deliverable\\_4\\_2\\_1.pdf](http://www.druid-project.eu/cln_031/nn_107548/Druid/EN/deliverables-list/downloads/Deliverable_4_2_1,templateId=raw,property=publicationFile.pdf/Deliverable_4_2_1.pdf) - Deliverable 4.2.1.