# FIP STATEMENT OF PROFESSIONAL STANDARDS
# THE SUPPLY OF MEDICINES
# AFFECTING DRIVING PERFORMANCE

The danger of ability to drive being affected by taking medicines has attracted more attention in recent years. The fact that medicines, such as some antihistamines, which may be available without prescription, can cause drowsiness, is well recognised. And the use of prescribed medicinal substances, such as the benzodiazepines, has been shown to more than double the risk of involvement in traffic accidents resulting in injury. Other medicines may affect vision or hearing. Although these effects are more easily detected by patients than the effects of psychotropic medicines on behaviour, people should be advised not to drive or operate machinery if vision is blurred or hearing impaired. Patients who are not advised properly on these issues by physicians and pharmacists have an increased risk of being involved in accidents, but may be unaware of this fact. People have a right to receive adequate information to enable them to decide whether or not it is safe to drive or operate machinery.

In pharmaceutical care, it is becoming standard practice to follow up patients who have indicated medicines-related problems that cause treatment failure or harm to the patient. For pharmacists who have built trusting relationships with patients, it is feasible to extend their services to include a duty of care for safe use of medication.

In practice, pharmacists update their knowledge about the effect of medicines on performance from four major sources: - the summary of product characteristics and package inserts approved by the regulatory authorities, articles in scientific journals and bulletins about medicines, and product specific mailings by pharmaceutical manufacturers.

Clinicians know that medication can produce unpredictable effects on performance. Clinical experience shows that the side-effects of a medicine vary from person to person and are compounded by polypharmacy and by self-medication while taking prescribed medicines. Impairment is often greater when medicines are taken in combination with alcohol. The situation can be further complicated by the fact that some medical conditions, such as epilepsy, allergic rhinitis and depression may themselves impair driving, if not treated properly with medication. The general principle that should be followed, where a suitable medicine is available, is that it is usually best clinical practice to prescribe, or for self medication to recommend, the medicine in the relevant therapeutic class that is least likely to impair performance.

Information concerning the increased potential for risk of being involved in an accident as a consequence of taking a medicine that is likely to affect driving performance, must be communicated to patients in a manner that ensures the information is fully understood. A simple way to achieve this would be by means of clear warning labels on the outer package and the container. Most countries, however, do not require warnings on the exterior packaging of prescription-only medicines, and patients are informed about impairment effects only by the package insert. Unfortunately, many warnings about the potential effect on driving performance provided by manufacturers, for these medicines, are found to be vague, illogical and sometimes misleading. In general, the pattern the warning follows starts with a list of the medicine's effects on the central nervous system. There is then a statement that these effects may impair mental and/or physical abilities required for the performance of potentially hazardous tasks. The warning ends with advice that patients should be told to use caution in undertaking such activities until their individual responses to the medicine have been well established. There is generally no advice about how to assess or recognise the individual patient's susceptibility to impairment.

For medicines available without prescription, any cautionary wording on the outer packaging should be brought to the attention of the potential purchaser and appropriate advice on alternative products given when appropriate.

For prescribed medicines, guidelines for dispensing practice must ensure that patients will obtain maximum benefit from the pharmacist's knowledge. Ideally, all advice given to patients will have the approval of the respective professional organisations of physicians and pharmacists. In ad-

dition, current knowledge of categorisation of medicines should be used to adjust the existing guidelines for all major medical conditions for which psychotropic medicines are prescribed. In other words, if psychotropic medication is the selected treatment option, the guidelines must refer to the benefits of using the least impairing medicine within each therapeutic class. A new warning system based on consensus among scientists worldwide and introduced in 1991 was intended to replace the dichotomous systems, based on medicinal class warnings1. The major improvement of the new system was its scheme for categorising medicines according to their potential for impairing driving skills.

Patient education has to be a substantial part of guidelines for dispensing. Patients need to be informed about how to detect any undesirable effects on psychomotor functioning at the start of treatment and at all follow-up visits if repeat medications are prescribed.

Against this background, the **FIP recommends** that pharmaceutical organisations should

• produce clear guidelines, reflecting the relevant current knowledge, designed to ensure that people are provided with adequate information to enable them to decide whether or not to drive or operate machinery after taking a medicinal product with potential effects on psychomotor performance.

• discuss with professional organisations of physicians and other prescribers and make joint efforts to improve prescribing practices relating to medicines with potential for impairing the performance of patients who drive or operate machinery and to encourage their members to prescribe the least impairing or safest medicine within each class, rather than those likely to cause more impairment.

• liaise with national regulatory authorities for medicines, to highlight the importance of warnings on labels and package inserts about possible effects on driving performance being clear, unambiguous and easy to understand. For medicines available without prescription, guidelines should specify that advice should be given in the pharmacy on the potential of various medicines, in the therapeutic category requested, to cause drowsiness or other impairment and, in relevant circumstances, those least likely to do so be recommended for use.

**For prescribed medicines, the dispensing guidelines should include information**

• to make it clear that the use of some psychotropic medicines has been associated with an increased risk of causing an accident leading to injury and that patients should receive this information.

• that pharmacists should discuss with prescribing physicians what patient information (written and oral) should be provided with the first supply of each medicine likely to cause impairment of performance.

• that encourages pharmacists to use published evidence to highlight differences in effect on driving performance of various medicines within the same therapeutic class.

• to inform the prescribing physician when more suitable alternatives exist, if a medicine has been prescribed that is likely to produce moderate or severe adverse effects or is presumed to be potentially dangerous, and the patient be appropriately informed.

• that the physician should be advised to prescribe the lowest effective dose of a particular psychoactive medicinal product and, if possible, to avoid multiple dosing during the day and the patient be appropriately informed

• that if the patient reports a lack of efficacy at the prescribed dosage, the physician be advised to consider an alternative medication rather than increasing the dose, and the patient be appropriately informed. If, however, there is no satisfactory alternative and a higher dose is therefore required, the patient be advised to take the largest part of the prescribed daily dose at bedtime.

• to explain to the patient that poly-therapy with psychoactive medicines will almost certainly impair the ability to drive or operate machinery safely, and to avoid doing so if treatment cannot be adjusted.

• to inform the patient, when appropriate, that alcohol increases impairment.

• that pharmacists should provide information, additional to that provided by the manufacturer, to clarify the warnings about any potential effects on driving performance.

• to advise patients about the ways they can recognise signs of impaired driving performance, if it is impossible to avoid them taking a medicine that will obviously impair performance, or one with an unknown potential for impairment.

• to monitor the patient's experience of driving while taking a medicine, for example when the first repeat supply is requested and report appropriately to the prescribing physician or ask the patient to do so.

**References:**

**(1)** International Council on Alcohol, Drugs and Traffic Safety (ICADTS) Working Group on Prescribing and Dispensing Guidelines for Medicinal Drugs affecting Driving Performance (2001).
Available at the ICADTS website:
http://www.icadts.org/reports/ICADTSpresguiderpt.pdf