

Proposed new drug driving regulations in Scotland

The Royal Pharmaceutical Society (RPS) is pleased to have the opportunity to respond to your consultation on new drug driving regulations.

We previously responded to the consultation in England and Wales in 2013, and understand that the proposed changes in regulations mirror those implemented in 2015 as a result of that consultation.

The response below is an updated version of that response which draws on the specialist knowledge of the UK Clinical Pharmacists Association specialist pain group and the Scottish Specialist Pharmacist in Substance Misuse group. (SPiSMs)

Our thanks go to both groups for their expertise in this clinical area.

General Comments

The principle of anti-drug driving legislation is supported as a measure to improve public safety.

Metabolism of drugs is a complex multifactorial therapeutic area. Blood levels and corresponding levels of impairment can vary widely in individual patients. These regulations provide a pragmatic solution that attempts to differentiate between illicit drugs for which there should be 'zero tolerance' and drugs prescribed for legitimate therapeutic purposes where individual variation in response is acknowledged and so a risk based approach to determination of blood levels is more appropriate.

The provision of a medical defence will help protect individuals who have been prescribed opioids and other drugs. However, the evidential burden is placed upon the person accused of committing an offence. Dispensed medicines have labels advising when caution is required before driving or operating machinery, but the healthcare professional issuing the prescription is unable to ensure that the medicine is being taken or used as intended. They are also unable to ensure that the patient does not have other illnesses or symptoms that may affect the way the body handles the drugs (e.g. dehydration or fever may be important for transdermal preparations).

Whilst there is evidence that medication taken for pain may impair an individual's ability to drive safely, and patients should not drive whilst their ability to drive safely is impaired, the fact that uncontrolled pain may also impair driving ability also needs to be considered.

The proposed legislation does not take account of the fact that patients may be prescribed other drugs for pain relief, such as tricyclic antidepressants and/or anti-epileptics, in addition to opioids that may also have an impact on driving ability.

Consideration also needs to be given to the potential synergistic effects of consumption of more than one drug where individually all are below the permitted threshold but where the cumulative effect results in impaired ability to drive. It is not clear how this will be addressed. This applies to combinations of prescribed and over the counter medications.



Morphine

Although the proposed threshold blood level for morphine (80 microgram/L) has been estimated to be equivalent to approximately being prescribed morphine sulphate 208 mg/day, this may still affect a small but substantial number of patients. In addition, the bioavailability of morphine shows considerable variability between patients and this will influence the blood level achieved for a given dose. The range of the different formulations of morphine available further complicates this as it is possible that driving may be impaired more if the total dose is taken as immediate release tablets or oral solution rather than modified release preparations which produce a relatively constant blood concentration.

The use of 6-acetylmorphine as a marker for heroin is an appropriate way of attempting to differentiate between ingestion of heroin and morphine.

Morphine is still considered by many clinicians to be the first-line strong opioid. As the proposed legislation does not propose limits for other commonly prescribed opioids such as oral oxycodone, transdermal fentanyl and transdermal buprenorphine, one of the unintended consequences of this legislative change may be that morphine is bypassed and the alternatives prescribed more frequently. This would be in direct opposition to several Health and Social Care Partnership prescribing formularies and the well-established governance around prescribing budgets. It could increase expenditure, with no advantage to patient care, as these are much more expensive than morphine.

Ketamine

Although ketamine is used mainly as an anaesthetic there a small number of patients who are prescribed ketamine for persistent pain. It is often supplied as a 'special' for named patients and the majority will be prescribed by specialist services from secondary care, or from hospices or other non-NHS palliative care services. The proposed blood limit for ketamine is rather low and this may mean that patients taking ketamine as prescribed may be arrested, although they would still be able to rely upon the medical defence if relevant. We recommend that Police Scotland is informed to make them aware of this situation.

Methadone

There are some legitimate concerns relating to patients prescribed methadone for opiate substitution therapy and the large variability and unpredictability of blood levels outside the expected limits with no apparent functional impairment. There is a wide range of doses from the titration doses of 10-40mg daily to the normal therapeutic range of 60-120mg daily and to prescribed doses in excess of 120mgs.

Currently a patient taking a prescribed drug like methadone would not automatically be considered by the courts to be unfit to drive and what dose is safe will depend upon the individual's stage of treatment, tolerance and history of licit and illicit drug use. For example, in the early stages of treatment an individual on a low starting dose of methadone may be impaired and unfit to drive with blood levels substantially below the proposed serum level of 500 micrograms /L and others prescribed significantly higher doses with serum levels in excess of the recommended limit may exhibit no functional impairment.

Any changes should be monitored to ensure that the implementation of any legislative change does not have unanticipated consequences that would adversely affect an individual's recovery. For example, there may be a reluctance to increase a dose of methadone to adequate therapeutic levels or a premature and unsafe reduction in dose due to the perceived implications of blood levels and driving. This could result in suboptimal dosing for non-clinical reasons leading to poor outcomes for patients.

One area which requires further consideration is that of co-prescribing where classes of drugs such as antipsychotics, antibiotics, anticonvulsants and a range of other drugs may interact with methadone to alter its' metabolism leading to potential increases in serum levels.

Amphetamine

This needs separate expert consideration. Adult ADHD remains controversial – both in terms of its diagnostic validity and treatment. The high threshold level set by the expert panel (600 micrograms/L) might be the best argued evidence based threshold which could be acceptable in combination with the necessary medical certification of ability to drive of a treated ADHD sufferer. This would avoid stigmatising young people with ADHD who wish to drive.

Recommendations for next steps

Robust and detailed advice will be required to allow healthcare professionals to provide a consistent and correct message to patients and the public about the impact of the proposed legislation.

An information and education programme for both the public and for health and social care professionals is essential as the consultation recognised that measures would have to be taken to increase awareness of the potentially additive effect of medications on driving ability. This should make reference to the effects of prescribed and OTC medications and also the impact of alcohol.

New issues will continually emerge. Medicinal Cannabis will need to be given consideration, as specialist clinicians are now able to legally prescribe Cannabis-derived medicinal products to patients with an exceptional clinical need.

The escalating numbers of new psychoactive substances could pose a particular problem for the future. Their consumption and probable detrimental effects on driving performance would essentially be excluded from the proposed legislation.

We recommend that the expertise of the specialist pharmacists in substance misuse and mental health is used to make sure all the unintended consequences of any proposals are fully explored; to consider emerging new drug issues as they evolve and to support the governance arrangements that are put in place.

We hope you find these views helpful and would be happy to discuss any of the issues raised in more detail with the committee.

For further information, please contact:

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