Regulations to specify the drugs and corresponding limits for the new offence of driving with a specified controlled drug in the body above the specified limit – response from the United Kingdom Clinical Pharmacy Association

The United Kingdom Clinical Pharmacy Association (UKCPA) is an organisation for pharmacists, technicians and health care professionals who provide clinical pharmacy services to patients and that promotes expert practice in medicines management and strives to foster and support excellence in clinical pharmacy practice in order for practitioners to provide outstanding patient care. The UKCPA welcomes the opportunity to respond to the proposed regulations to specify the drugs and corresponding limits for the new offence of driving with a specified controlled drug in the body above the specified limit.

The UKCPA Pain Management Group has specialist interest and knowledge in relation to analgesics, including opioids, ketamine and cannabinoids in particular. Whilst there is evidence that medication taken for pain may impair an individual's ability to drive safely, and while it is reasonable to suggest that patients should not drive whilst their ability to drive safely is impaired, this must be balanced against an individual's ability to live as normal a life as possible and maintain his or her independence. 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 or taking 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. Robust and detailed advice will be required to allow healthcare practitioners to provide a consistent and correct message to patients and the public about the impact of the proposed legislation.

Question 1.
Do you agree with the Government's proposed approach as set out in policy option 1? If not please provide your reason(s).

Policy option 1 provides a pragmatic solution that attempts to differentiate between illicit drugs for which there should be 'zero tolerance' and controlled drugs prescribed for legitimate therapeutic purposes where 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. Although a prescription may be provided for a legitimate purpose the healthcare professional issuing the prescription is unable to ensure that it is being taken or used as intended. The healthcare professional is also unable to ensure that the patient does not have concomitant illness conditions that may affect the way the body handles the drugs (e.g. dehydration or fever may be important for transdermal preparations).

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 different formulations of morphine that are available further complicates this as it 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 that 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 and this may increase expenditure as these are much more expensive than morphine.

Question 2.
Do you have any views on the alternative approaches as set out in policy option 2 and 3?
The UKCPA would wish to ensure that opioids remain available for those patients for whom they are effective and necessary analgesics that provide beneficial improvements in pain intensity and other functional outcomes.

Both policy option 2 and policy option 3 do not sufficiently differentiate between illicit and therapeutic uses of controlled drugs. Policy option 2 proposes adoption of a risk based limit for each drug whilst policy option 3 would take a zero tolerance approach for the specified controlled drugs.

Question 3
We have not proposed specified limits in urine as we believe it is not possible to establish evidence-based concentrations of drugs in urine which would indicate that the drug was having an effect on a person's nervous system. Do you agree with this (i.e. not setting limits in urine)? Is there any further evidence which the Government should consider?

The UKCPA agree with this approach. The concentration of a drug and/or its metabolites in urine varies even more than in plasma and oral fluid and the volume of urine must be considered as well as the concentration in order to assess the amount of drug ingested. Hence, it would be much more difficult to provide levels in urine for drugs used for therapeutic purposes.

Question 4.
Is the approach we are proposing to take when specifying a limit for cannabis reasonable for those who are driving and being prescribed with the cannabis based drug Sativex (which is used to treat Multiple Sclerosis)? If not what is the evidence to support your view?

This appears to be a reasonable and pragmatic approach.

Question 5.
Do you have a view as to what limit to set for amphetamine? If so please give your reason(s).

No.

Question 6
Are there any other medicines that we have not taken account of that would be caught by the 'lowest accidental exposure limit' we propose for the 8 illegal drugs? If so please give your reason(s).

Although ketamine is used mainly as an anaesthetic there is evidence for clinical effectiveness for some types of persistent pain. A relatively small number of patients are prescribed ketamine for persistent pain. The Prescribing Cost Analysis (from the Health and Social Care Information Centre) probably underestimates the number of prescriptions issued for this indication as it is often supplied as a 'special' 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 these 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 the Association of Chief Police Officers is informed to make them aware of this situation in a similar way to that proposed for Sativex.

Diamorphine tablets are available although they are prescribed infrequently.

Question 7

Are you able to provide any additional evidence relating to the costs and benefits associated with the draft regulations as set out in the Impact Assessment at Annex D? For example:

i. Do you have a view on the amount of proceedings likely to be taken against those on the medical drugs proposed for inclusion under the approach in Policy Option 1? If so please give your reason(s).

ii. Do you have a view on the methodology used to estimate the amount of proceedings? If so please give your reason(s).

iii. Do you have a view on the methodology used to estimate the drug driving casualties baseline? If so please give your reason(s)

iv. Do you have a view on the methodology used to estimate the casualty savings? If so please give your reason(s).

v. Do you have a view on the methodology used to estimate those arrested on a credible medical defence under Policy Option 3? If so please give your reason(s).

Question 8

Does any business have a view on whether the Government's proposals will have any impact on them, directly or indirectly? If so please give your reason(s).

The proposed legislation may have an impact on individuals whose work requires them to drive (e.g. lorry drivers, taxi drivers) and who are taking analgesics for pain relief. This in turn this may have consequences for businesses that employ these individuals.