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13 September 2013

Dear Martin,

**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 – A Consultation Document**

Response from LGC Limited

As, Chief Scientific Officer of LGC I have responsibility for overall science strategy and for developing and joining up science across LGC. I am pleased to be able to respond to this consultation. LGC has a wide range of expertise upon which I can draw, specifically from LGC Forensics, which has significant experience and expertise in forensic drugs and toxicological analysis.

I have looked at the consultation and can respond to some sections where there is an analytical measurement dimension or where we have specific expertise and experience.

Q1: Do you agree with the Government's proposed approach as set out in policy option 1?

*I do not fully agree with this proposed approach.*

*Of the drug positive samples tested at LGC between 2008 and 2012 benzodiazepines were the second most prevalent at 26%, after cannabis, and opiates the fourth most prevalent at 17 % of samples. These medicinal drugs represent a significant road traffic risk, and we believe that they should therefore be included.*

*We believe that there is no need to set the limits for these medicinal drugs at a high level. Prescribed users will be able to claim the medicinal defence even when the limits are set lower. Lower limits will enable the prosecution of unprescribed use.*

*We do not agree with the inclusion of 6-Monoacetylmorphine. This metabolite arises from the breakdown of diacetylmorphine, but has a very short half-life and therefore it unlikely to be found in a driver's blood sample taken at a Police Station. The use of morphine, which has a longer half-life, would be a better option as a heroin metabolite. Any driver using morphine under prescription has the medical defence option available.*

*I believe that the further development of reliable, validated roadside testing devices should be encouraged; these would further reduce the time between incident and sampling.*

Q2: Do you have any views on the alternative approaches set out in policy option 2 and 3?

*The approach in option 2 of linking limits to known increased road traffic risk while eliminating the 'false positive' results will, in my opinion, generate an overwhelming number of 'false negative' results. It would not be consistent with the desired, 'don't drug and drive', message.*

*My preferred option is option 3. I can not entirely agree with the argument against this option. The result of any blood test will not be known until after the analysis. The samples will have been taken as there is already reason to believe that the subject is unfit through drugs. The use of the medical defence will move the charge from section 5A to Section 4 allowing prescribed medicinal users to ensure that any impairment evidence is properly examined in court.*

Q3: We have not proposed specified limits in urine as we believe that it is not possible to establish evidence-based concentrations in urine which would indicate that the drug was having an effect on a person's nervous system. Do you agree with this? Is there any further evidence which the Government should consider?

*I agree that the concentration of drug in urine bears no relationship with the concentration in blood.*

Q4: 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?

*Any driver using Sativex under prescription has the medical defence option available.*

Q5: Do you have a view as to what limit to set for amphetamine? If so please give your reason(s).

*Yes. A limit can and should be set. As with the other medicinal drugs the medical defence will be available to prescribed users. I believe that the limit should be 50ug/L, and a cumulative approach should be used to amphetamines as in France. Lower levels could catch prescription drugs which metabolise to amphetamine*

Q6: 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?

*Ketamine is still administered medicinally in some circumstances. It would still have the medical defence option so perhaps could be ignored.*

Other General Comments:

*I am concerned by the recommendation to include Benzoyllecgonine (BZE) on the list at a limit of 50 µg/L. BZW is an inactive metabolite of cocaine with a long half-life in the body. If found at 50 µg/L it is likely for cocaine to have been used many hours before driving. The original recommendation of the expert panel was a limit of 500 µg/L BZE which would be more appropriate.*

*I am also concerned about the list of benzodiazepine drugs as listed in Annex C of the draft regulations. Clonazepam is not at all commonly used, but if it is to be included, then it would make sense to also include alprazolam and phenazepam which can also cause*

*similar impairment. This would be in line with the National Police Forensic Framework's view on benzodiazepines.*

*The analysis of all the drugs listed in the draft regulations is also a cause for some concern. If these analyses are compared with the analysis of alcohol, in the drink-driving scenario, then a number of significant differences need to be noted. The quality of alcohol measurements is significantly better as there are Certified Reference Materials (CRMs) available to demonstrate accuracy and to give lower measurement uncertainties. Measurement uncertainties for the analysis of drugs in blood are usually of the order of 20-30 %. Equivalent CRMs do not exist for drugs in blood at present, and I believe that in order to move towards more reliable measurements for these drugs, then CRMs need to be developed. Until this has been successfully achieved, all laboratories carrying out these measurements must be accredited for those measurements and participate in appropriate proficiency testing (PT) schemes which are designed to cover the range of drugs listed in the draft regulations.*

Thank you for this opportunity to comment.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Derek Craston', written in a cursive style.

**Derek Craston**  
**LGC Chief Scientific Officer**